Annual Report 2019

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Contents

2019 Statistics at a Glance

Top 5

The HPRA was among the top five contributors at EU level for lead assessment of centrally authorised medicines & scientific advice

300+

delegates attended the HPRA Brexit information day in February

554

The number of Reference Member State transfers to Ireland for human and veterinary medicines in advance of Brexit

102

The number of European Medicines Agency scientific advice procedures for human medicines co-ordinated by the HPRA

40

medical devices organisations registering with the HPRA as EU Authorised Representatives following impact of Brexit

433

new human medicines authorised during 2019

88

applications issued for clinical trials of human medicines

24

HPRA experts acted as rapporteur or co-rapporteur in respect of 24 new centrally authorised veterinary medicines

159

manufacturing licences in place at year end – 135 for human medicines and 24 for veterinary medicines

4,077

export certificates issued – 1,367 certificates for medicines and 2,710 free sale certificates for medical devices

55

The HPRA was EU rapporteur for the management of any safety signals detected in relation to 55 centrally authorised human medicines

9,253

suspected adverse reaction reports for human medicines received

347

reports of suspected adverse reactions associated with use of veterinary medicines

2,295

medical device vigilance reports received and assessed

1,654

market surveillance cases undertaken in respect of medical devices

132

medicine recalls consisting of 125 human medicines and 7 veterinary medicines

110

GMP inspections conducted at manufacturing sites for human and veterinary medicines, and active substances

287

reactive surveillance cases initiated for cosmetic products

1,018,678

dosage units of fake (falsified) and other illegal medicines detained

4.4 million

page views on the HPRA website – the highest ever annual figure

Chairperson's Statement

It is with great pleasure that I present the 2019 annual report of the Health Products Regulatory Authority (HPRA). Without doubt, this was a year that brought many new developments and changes within both the internal and external environments. I am immensely proud of the way the organisation planned for and adapted to the opportunities and challenges that presented during the year, while steadfastly maintaining its primary focus on the protection of public and animal health.

Preparing for Brexit

A key area of focus for the agency during the year was its planning for Brexit in the context of the high profile deadlines in place and set against the uncertain political backdrop that ensued beyond our shores. The HPRA showed great leadership throughout this time, working closely with our partners across the health sector to ensure minimum disruption to the continued supply and availability of medicines and medical devices for Irish patients.

The HPRA's focus centred on five key Brexit pillars, previously identified as part of its planning and contingency processes. These pillars, as set out below, served as the agency's guiding principles as it implemented and delivered detailed Brexit preparations and provisions:

1. Stakeholder engagement and communications;
2. Existing work where the UK is a lead member state;
3. Future work to be allocated;
4. Leadership/public health/advocacy;
5. Internal capability.

At all stages, working in partnership with the Department of Health and the HSE, the HPRA worked to build collaboration and consensus with other stakeholders to ensure that we were appropriately positioned to deal with any potential supply issues.

In particular, there was a focus on delivering regulatory responsiveness and flexibility to aid swift actions to be taken as required. I am confident that with this high standard of preparedness, planning and engagement, we remain ready and well-positioned to manage any issues in relation to health product supply that could emerge when the UK fully exits the EU. No doubt, this will be a focus of my annual statement again for 2020.

Increasing our Contribution at a European Level

Another key development during 2019 was the change in profile and increase in the HPRA's contribution to the centralised assessment procedures at the European Medicines Agency (EMA). By the end of the year, the agency became one of the top five contributors in terms of its work on lead assessments for centrally authorised medicines and scientific advice. This significantly enhanced contribution during 2019 represents the outcome of a series of planned measures, overseen by the Authority, which were introduced over the past number of years to increase the HPRA's scientific expertise and refine our focus on supporting and enabling innovation. This ongoing prioritisation and investment will ensure that the HPRA continues to act as a lead agency within the centralised system that enables access to innovative treatments and medicines for Irish patients and all European citizens.

A major highlight of the year was the appointment of our Chief Executive, Dr Lorraine Nolan, to the prestigious post of Vice-Chair of the EMA Management Board. This further demonstrates the HPRA's commitment to supporting the European regulatory network for human and veterinary medicines and is a testament to Dr Nolan's contribution and expertise.

Other Changes within the Authority and Broader Organisation

At the close of 2019, we prepared for a notable change in the composition of our Authority when the most recent terms of two longstanding members, Pat Brangan and Wilf Higgins, came to an end. Both gave long, loyal and expert service to the workings of the Authority during their tenure. Pat additionally held the Chair both of the Advisory Committee for Veterinary Medicines and the Audit and Risk Committee, while Wilf was Chair of the Advisory Committee for Medical Devices. They were strong and effective contributors at our Authority meetings, not just across their respective areas of expertise, but in all deliberations and discussions. Both Pat and Wilf gave freely of their vast knowledge and experience, and provided huge dedication and commitment to public sector delivery in Ireland. I thank them both sincerely and pay tribute to them as valued members of the Authority.

This year, we welcomed one new Authority Member, Professor David Kerins. David is already contributing effectively to the Authority and has taken on the role of Chair of the Advisory Committee for Human Medicines.

We were very saddened during the year to hear of the untimely passing of our previous Chairman, Michael Hayes. Michael served as the Chairman of the Authority from 2011 to 2016 and was a strong leader and good friend to us all. Ar dheis Dé go raibh a anam.

Also in 2019, we also bade farewell to Dr Joan Gilvarry following her retirement from the role of Director of Human Products Monitoring. Dr Gilvarry provided over 25 years of service to the HPRA in a number of roles. Her professionalism and expertise was valued highly throughout her career by her colleagues within the HPRA.

The Future

Looking forward, the Authority is now overseeing the development of the HPRA's Strategic Plan for the period 2021 to 2025. To fully inform and assist the process, we held a number of focussed strategy sessions at Authority and executive levels, while there has been significant engagement internally with staff and externally with a broad range of interested stakeholders. The outcome of this ongoing and extensive consultation process, which commenced in 2019, will reflect the changing environment in which the HPRA operates and the evolving needs and requirements of the health products regulatory system of the future.

The outcome of this extensive preparatory exercise will deliver a strategic roadmap setting out clearly how the HPRA will continue to evolve and progress as an organisation while delivering its key public and animal health objectives for the benefit of all our partners and stakeholders.

This is an exciting period in the development of our national regulatory authority. The HPRA is privileged to oversee the regulation of a number of dynamic and innovative sectors in Ireland that play such a central role in the protection and enhancement of public and animal life not just nationally but right across the world. A key focus, as always, will be on facilitating the availability of medicines and medical devices. However, it is also recognised that the existing regulatory model must continually evolve and respond to an ever-changing environment where the latest technologies and product innovations, coupled with increasing access to data and intelligence, are driving the development of new life-changing and life-saving health products.

As part of its ever-developing strategic vision, the HPRA will continue to build mutually beneficial partnerships with relevant agencies across the public sector, with regulators internationally and with patients and healthcare professionals. Significant and meaningful engagement with patients and the broader health sector is central to our future effectiveness and we will never lose sight of our core mission to work on behalf of all those who use and benefit from health products.

Acknowledgements

On behalf of the Authority, I wish to extend our gratitude to the Minister for Health, the Minister for Agriculture, Food and the Marine, their advisors and the staff of their departments for their continued support of the HPRA and its wide range of activities.

I would also like to express my sincere appreciation to the members of the Authority and to the Chairs and members of the HPRA advisory committees and subcommittees who gave freely of their time and expertise throughout 2019. The continued contribution of independent experts to the HPRA is highly valued and is of significant benefit to the regulatory process.

Finally, I would like to thank the Chief Executive, management and all staff for their dedication, hard work and professionalism throughout the year. The ongoing commitment of all areas of the organisation to protect human and animal health is clear to see throughout the HPRA's 2019 annual report.

Ms. Ann Horan
Chairperson

Authority Members

The Authority of the HPRA is appointed by the Minister for Health in accordance with the powers conferred by subsection 2 of section 7 of the Irish Medicines Board Act, 1995. The members of the Authority during 2019 were:

Ms. Ann Horan
(Chairperson)

Mr. Pat Brangan
Term ended 31 December 2019

Mr. Wilfred J. Higgins
Term ended 31 December 2019

Mr. David Holohan

Mr. Brian Jones

Dr. Elizabeth Keane

Prof. David Kerins
Appointed 22 March 2019

Prof. Caitriona O'Driscoll

Dr. Diarmuid Quinlan

Management Committee

Dr. Lorraine Nolan
Chief Executive

Ms. Rita Purcell
Deputy Chief Executive

Dr. J.G. Beechinor
Director of Veterinary Sciences

Ms. Sinead Curran
Director of Human Products Monitoring
Appointed December 2019

Dr. Caitríona Fisher
Director of Quality, Scientific Affairs and Communications

Mr. John Lynch
Director of Compliance

Dr. Niall MacAleenan
Deputy Director of Medical Devices

Ms. Lynsey Perdisatt
Director of Human Resources and Change

Ms. Grainne Power
Director of Human Products Authorisation and Registration

Chief Executive's Report

As always, it is a great pleasure to give my foreword to the HPRA's annual report and to highlight the achievements of the year that has past.

The Decade in Review

2019 was not only a year during which our organisation had many successes, but it also saw the close of the decade. Reflecting on this ten-year period, we have seen a time of intense growth and development for our agency and a time during which many ambitions have been realised. The remit of the organisation expanded to include new areas such as scientific animal protection and monitoring of the safety and quality of organs used in transplantation. We also successfully adopted our new HPRA name and brand. This change was driven by the need to reflect the extensive range of our remit, which covers multiple health products, most notably medicines and medical devices.

I believe the most striking developments for the HPRA in this time period have been on two fronts. The first relates to the emphasis we now place on collaboration in carrying out our role, which serves to ensure better outcomes in public and animal health protection. Those partnerships have been brought about by the development of positive working relations and approaches with multiple stakeholders including those with direct responsibility across government for health service delivery, healthcare professionals and patients.

The second area where we have brought about significant progress is our positioning as an influential leader in both the European and global regulatory networks. We have invested strategically over the past decade in chosen areas of expertise and capability, and in our contribution to leading regulatory fora and structures at an international level. Through this, we have achieved leadership roles within the Heads of Medicines Agencies (HMA) network, the Competent Authorities for Medical Devices (CAMD) and various European Medicines Agency (EMA) scientific committees, task forces and working groups. We have also made very significant advancements in our contribution to EMA scientific assessment and inspection activities. On a personal level, I was very proud to be appointed as the Vice-Chair of EMA's Management Board during 2019. As we move forward in the post-Brexit era, our capability to influence and build positive working relationships with colleagues across the European and international networks is more important than ever.

Brexit

As was the case for so many organisations, 2019 was a year characterised by our work in dealing with the numerous and unprecedented challenges presented by Brexit. I am extremely grateful for the extensive work done by colleagues from across the organisation in preparing for the various political deadlines throughout the year. At all stages, we remained fully committed to prioritising public health needs over all matters. Collaboration with both the Department of Health and the Health Service Executive (HSE), and engagement with industry stakeholders, were steadfast throughout and ensured our preparedness for all outcomes. As we look ahead to the end of 2020, we are confident in the investment we have made in Brexit preparations and that we are ready for the full UK exit regardless of how that may occur.

Shortages Framework

One of the most important public health initiatives that the organisation has undertaken in recent years has been the framework we implemented to ensure enhanced management of medicines shortages nationally. Medicines shortages are an increasing trend for all countries regardless of size or economic positioning and are brought about through multiple factors. Our shortages framework operates by enhancing coordination across the various stakeholders that have a role in the management of shortages. Since its implementation, it has been highly successful in ensuring optimal outcomes for patients and protecting healthcare provision capability. Throughout 2019, our processes for managing shortages were further enhanced through the establishment of a forum between the HPRA, Department of Health and HSE to assess critical dependencies on medicines in the context of healthcare delivery in Ireland. As a result, we now have a new level of intelligence to support our work in the area of shortages to provide for better proactive management. This will be hugely beneficial for patients and our health system in the years ahead.

Our People and Processes

As an organisation, we are fully committed to continued investment in everyone who works in the HPRA and in the systems and processes that support them. We place huge value on developing our internal capabilities as this is key to enabling our future progress. For the past number of years, we have placed significant emphasis on developing and expanding our scientific expertise and capability. This has been driven by a strategic objective to better support the pace of innovation in the sectors that we regulate and to increase our contribution to the centralised assessments of medicines co-ordinated by the EMA. In 2019, we were very proud to realise part of this objective after being ranked within the top five agencies contributing to the scientific assessments of both medicines for human use and medicines for veterinary use. Given the pace of innovation in the sectors that we regulate, the increasing trends of product complexity, digitalisation and convergence, and the sophistication in technology and processes, expanding expertise and skills will continue to be a focus for the HPRA.

During 2019, our change management programme for our medical device activities continued. The impetus for this programme has been enhanced positioning of our capabilities to regulate the highly innovative medtech sector and to prepare for the implementation of the new legislative framework for medical devices in Europe over the next three years. A number of key milestones were reached during the past 12 months, including the implementation and roll-out of a revised departmental structure based on technology streams. This provides a more dynamic and agile approach to resourcing, which positions us with improved capabilities in the context of product convergence and technology development. This overall approach represents a very exciting development in our internal resourcing model and is something we intend to replicate in other areas.

Another focus during the year was the roll-out of our ongoing technology project focused on enhancing our workflow capability. 2019 saw our medicines assessment activities incorporated into the new workflow system. We look forward to the opportunities ahead in 2020 and beyond as we work to develop a longer-term digital transformation strategy for the organisation.

The health and wellbeing of our organisation is one of our greatest assets and we work hard to promote a positive working environment within the HPRA. This is part of our culture and central to our value

system. Some of our proudest achievements as an organisation last year included the launch of our Diversity and Inclusion Policy, which was supported by a number of focussed initiatives in this area. We were thrilled to have our work externally recognised with receipt of an Investors in Diversity award. In 2019, the HPRA also became a partner to See Change, a national programme aimed at ending mental health stigma. This is another important milestone in our organisation's health and wellbeing journey and signals our enduring and sustained commitment to this cause.

Looking Ahead

We must always keep focussed on the future and on our continued progression as an organisation. My colleagues and I are honoured to work in a public service area where every day we have the possibility to make a difference in enhancing the health of people and animals. With that honour, comes a responsibility to ensure we both sustain and develop our regulatory approach. In line with this, we are now actively working with our Authority to prepare the next iteration of our strategic plan. This is a very exciting and motivating time for our organisation as we define what our key goals will be over the next five years. We look forward to the opportunities ahead and continued success in protecting and enhancing public and animal health. The investments we have made in our people and processes, and the value we place on collaboration with our stakeholders, will ensure that we deliver on our commitment to serve as a trusted and progressive health product regulator.

Acknowledgements

I wish to acknowledge and thank the Ministers and staff of the Department of Health and the Department of Agriculture, Food and the Marine for their continued support.

On behalf of the Management Committee and all our colleagues, I wish also to acknowledge the significant contribution and commitment of the members of the HPRA Authority and advisory committees. Their advice and expertise is of great value to our agency and is much appreciated.

My sincere thanks as always to Ann Horan, our Authority Chairperson, for her huge commitment to the organisation and for her invaluable advice and counsel.

Everything the HPRA has achieved has been brought about through teamwork. So finally, to all my colleagues throughout our agency, I thank you for the excellent work in 2019, but also for your passion and commitment to our remit of public and animal health protection. You have brought about all our successes in the past decade. I am privileged to continue to work with you in ensuring high standards in health product regulation and, through this, playing our part in delivering better care and outcomes for patients.

Dr. Lorraine Nolan

Chief Executive

Planning for Brexit – Annual Update on Progress

The UK left the European Union on 31 January 2020 on the basis of the Withdrawal Agreement which was agreed by the European Council on 17 October 2019. The agreement includes a transition period until at least 31 December 2020. In March 2020, the EU and the UK began negotiations on a new future relationship agreement which, if agreed, is due to come into effect from 1 January 2021.

No matter what the final shape of Brexit looks like, the decision of the UK to leave the EU will result in changes to the European health products sector and regulatory network as a whole. The UK withdrawal from the EU has potentially significant implications for Ireland in particular given our shared marketplace and the fact that many health products are manufactured in or moved through the UK to get to Ireland. Consequently, the HPRA has been actively contributing to a whole-of-Government response to Brexit, which includes a range of measures to ensure the continuity of supply of health products.

HPRA Response to Brexit

Once Article 50 was invoked by the UK on 29 March 2017, the HPRA commenced our Brexit preparedness planning. The protection of public health by supporting the continued supply of health products after Brexit was identified as our key strategic objective while also optimising our role within the European regulatory network.

Adopting an organisation wide approach, an internal task force was established to inform internal and external planning as well as our communications and engagement activities.

As part of this approach, we developed the **five key pillars** to support delivery of our strategic objective and high level outputs:

Stakeholder Engagement and Communications	Stakeholder meetings, Q&As published, website content, one-to-one meetings with impacted stakeholders, presentations to industry meetings, media engagement.
Existing work where the UK is lead Member State	Committed to taking on all work where UK is the RMS and Ireland a CMS. Seeking newly available work under centralised system. Encouraging UK notified bodies to relocate to Ireland. Purpose: To maintain product on the market.
Future work to be allocated	Developing our capacity to bid for centralised and decentralised work to increase our European footprint and enhance our position as a leading EU regulator.
Leadership, Public Health and Advocacy	Ensuring the views of the Irish regulator are represented and understood at a European level. Proactively contributing to all EU Brexit meetings and engaging F2F with the Commission and the ENVI committee.
Internal Capability	Reviewing HPRA capacity to deliver on Brexit commitments. Staffing plan submitted to the Department of Health.

Key Brexit Pillars – Activities carried out in 2019

Building on progress achieved during 2017 and 2018, the following details the main activities and work streams delivered during 2019 in respect of our five Brexit pillars:

1. Stakeholder Engagement and Communications

- There was continued implementation of our programme of communications and outreach including regular and sustained contact with individual manufacturers, industry, wholesalers and distributors, in addition to their representative bodies. In response to a number of deadlines in 2019, where the UK could have left without a deal, we contacted all MAHs to ensure Brexit preparedness, supply chain and regulatory compliance, and engaged with wholesalers to understand critical products, potential supply issues and capacity for "buffer" stocks.
- Our detailed Brexit guidance document and website content were both updated to reflect queries received from stakeholders and emerging information from the European Commission, the EMA and the HMA. Updates were also made to the medical devices and cosmetic products section of the HPRA website to highlight potential impacts of Brexit.
- We presented at a number of industry seminars on the impact of Brexit and held a HPRA stakeholder information day in February 2019.
- There was regular staff communications in respect of Brexit planning.

2. Existing Work where the UK is Lead Member State

- We engaged with companies to facilitate the transfer of the RMS to the HPRA.
- We reviewed product exposure to the UK from a regulatory perspective and

contacted companies to request that they transfer necessary regulatory functions to the EU.

- We contacted companies who have a large portfolio of products on the Irish market to understand any future barriers to supply and we responded to any potential supply issue identified.
- We provided updates in respect of joint labelling with the UK and met with other EU agencies to assess the possibility of multilingual labelling.
- We concluded an agreement with the UK's Veterinary Medicines Directorate for a work-sharing arrangement post Brexit.

3. Future Work to be Allocated

- 554 RMS transfers to Ireland were accepted in 2019 (502 in 2018); 285 for human medicines (346 in 2018) and 269 for veterinary medicines (156 in 2018).
- In respect of new outgoing MRP/DCP applications for human medicines, we led as RMS for the assessment of 17 cases/29 products. In addition, we led as RMS for the assessment of 60 new MRP/DCP veterinary product applications including nine repeat use procedures.
- We were appointed rapporteur / co rapporteur for 18 centralised human medicines while also being appointed co rapporteur for nine centralised veterinary products.
- We acted as co-ordinator for 102 EMA scientific advice procedures for human medicines. We were also co-ordinator (two) or joint co-ordinator (two) for four procedures in respect of veterinary medicines.
- There was an increase in the number of medical devices organisations establishing in Ireland as a result of Brexit, with 40 organisations registering as EU Authorised Representatives with the HPRA. There were also 3,565 medical devices registered during 2019.

4. Leadership / Public Health / Advocacy

- We participated in extensive planning with the Department of Health, the HSE and the FSAI for Brexit. This took the form of weekly meeting, both at a strategic and operational level. We participated in key work initiatives on managing medicines and medical devices availability in the event of no deal.
- We participated in all Commission seminars and other EU meetings to advocate and promote greater understanding of the potential impact of Brexit for Ireland's.
- We led discussions at an EU level for the acceptance of dual labelling and for a pragmatic approach to contingency planning.
- There was also regular engagement with officials at the Department of Agriculture, Food and the Marine and the Department of Foreign Affairs and Trade.
- We engaged at a national level with the Revenue Commissioners with a view to minimising potential customs impact.
- We liaised with IDA Ireland, IBEC and industry representative bodies, and other stakeholders as appropriate.

5. Internal Capability

- Our Brexit planning includes due consideration of potential staffing requirements and we continued to work closely with the Department of Health on this matter.
- We are committed to ensuring that we have sufficient staff levels to manage the implications of Brexit and throughout 2019 we devoted expert staff resources to this important area through a combination of allocating existing staff as well as some new staff.

Contingency Planning for No-Deal Brexit

During the course of 2019, our Brexit planning was based on an initial no-deal outcome as of 29 March 2019, which was subsequently extended to 12 April, 31 October and 31 January 2020. As a result, all our guidance and direction to industry stakeholders was based on a requirement for them to carry out all their regulatory changes in advance of the various deadlines. This involved confirming that their supply routes were capable of continuing supply to Ireland and reviewing stock levels to ensure that they had sufficient product available in the event of issues affecting entry points to Ireland as well as those in the UK and Europe.

In 2019, the HPRA moved from operational planning to Brexit contingency planning under the following headings:

- Regulatory compliance of medicines and clinical trials authorised on the Irish market;
- Supply chain management and stock levels;
- Exempt medicinal products;
- Shortages protocol;
- Development of a list of essential medicines;
- Communications with stakeholders;
- Medical devices with UK CE marks;
- Veterinary medicines and engagement with the Department of Agriculture, Food and the Marine;
- Engagement within the European network.

As outlined, the withdrawal agreement provides for a transition period, which is due to expire on 31 December 2020. At time of publication, negotiations between the EU and the UK on a new future relationship agreement were ongoing.

Much of the extensive preparatory work carried out by the HPRA and other stakeholders in 2019 will remain beneficial and relevant particularly if no trade deal, or only a limited trade deal, can be agreed.

During the transition period, the UK remains subject to EU law and while it cannot act as a lead Member State and cannot be part of the EU institutions, it is still within the economic union and subject to medicines and medical devices legislation.

Human Medicines

The HPRA grants licences for medicines subject to a review of their safety, quality and effectiveness and continuously monitors their use once they become available on the Irish market. We also approve and monitor clinical trials, inspect and license manufacturing sites and wholesalers, and investigate activities associated with the illegal supply, manufacture or advertising of medicines.

Authorisation and Registration

- Prior to a new medicine being placed on the Irish market, it must be assessed and authorised (licensed) by the HPRA or by the European Medicines Agency (EMA) in conjunction with the European Commission. The assessment involves establishing that a medicine's health benefits outweigh its known risks. Where this is the case, it may be granted a marketing authorisation.

  There are a number of routes through which a product can be authorised by the HPRA. These include the national procedure, the mutual recognition procedure (MRP) and the decentralised procedure (DCP). Both MRP and DCP involve the simultaneous submission of applications in a number of EU Member States.

  The centralised route is co-ordinated by the EMA and results in an authorisation that is granted by the European Commission and is valid across Europe. The assessment is carried out by Member States appointed as lead assessor (rapporteur), joint lead assessor (co-rapporteur) and peer reviewer, with input also from all other Member States.

  During the year in review, the total number of new medicines authorised in Ireland was 433. The 2019 figure incorporates:

  – 49 new national applications including 34 parallel import applications;

  – 52 applications made under the MRP and 194 applications made under DCP. The HPRA acted as reference (lead) Member State for the assessment of 17 of these DCP applications;

  – Five rapporteurships and 12 co-rapporteurships under the centralised route;

  – An additional 121 medicines authorised through the centralised route where the HPRA was neither rapporteur nor co-rapporteur.

- The EMA operates a scientific advice and protocol assistance procedure system to applicants on the appropriate tests and studies in the development of a medicine. This is designed to facilitate the development and availability of high quality, effective and acceptably safe medicines for the benefit of patients. During 2019, the HPRA acted as co-ordinator for 102 EMA scientific advice requests across a broad range of conditions.

  Our national scientific and regulatory advice procedure functions in a similar way and assists commercial and non-commercial entities making applications for clinical trial authorisation or marketing authorisations. This service complements advice that we provide on earlier stage product development through the Innovation Office. During the year, we completed 20 requests under this procedure.

- Participation in clinical trials can enable patients to benefit from new and promising therapies. During 2019, we issued 88 new clinical trial applications. Of these, two applications were voluntary harmonisation procedures for clinical trials with the HPRA acting as lead Member State for these co-ordinated work-sharing assessments of multinational clinical trials.

- Reclassification of the legal status of medicines aims to increase the number of medicines available to patients without prescription where it is safe to do so. This year:
  - A medicine for the treatment of reflux symptoms (heartburn and acid regurgitation) was authorised for non-prescription, pharmacy-only sale.
  - A medicine containing folic acid was authorised for sale in pharmacies and non-pharmacy outlets (general sale).

- The HPRA publishes and maintains a list of interchangeable medicines to facilitate generic substitution by pharmacists and to allow for reference pricing by the Health Service Executive (HSE). By year-end, the interchangeable medicines list included 70 active substances.

- Medicine shortages have been an ongoing concern globally and in Ireland for some years. This year marked the first full year of operation of the Medicines Shortages Framework. This collaborative initiative brings together key players in the health sector with the aim of developing strategies to mitigate the effect of shortages in Ireland, thereby protecting patient health. Notable shortages addressed under the framework in 2019 included fentanyl injections (used in hospitals to prevent or relieve pain), total parenteral nutrition (used in hospitals for patients who have difficulty feeding) and ranitidine (used for conditions such as ulcers associated with stomach acid).

  Additionally, and in the context of Brexit, the HPRA has identified the use of multilingual labelling as a means of minimising the impact of the UK withdrawal on the availability of medicines in Ireland. Significant process was achieved during 2019 in moving forward with this initiative including:
  - The HPRA has taken the lead role within the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh) and has developed a 'Best Practice Guide on Multilingual Packaging' which is now available on hma.eu website. As part of this process, the HPRA CMDh member consulted with interested parties who provided positive feedback on the guidance particularly in respect of products authorised through the national route. Extensive feedback on the associated challenges faced by stakeholders was also received and Ireland is leading a group of selected CMD(h) member states to address these challenges further.
  - In parallel, the Irish member of the Quality Review of Documents (QRD) Working Group at the EMA is actively contributing to revision of the existing 'Compilation of QRD decisions on stylistic matters in product information' guidance. This will further facilitate the development of multilingual labelling for products intended for the Irish market but authorised through the centralised procedure.
  - The HPRA has updated its 'Guide to Labels and Leaflets of Human Medicines' to give detailed guidance to marketing authorisation holders (MAHs) on issues to consider when developing multilingual labelling. We have also confirmed that we are available to work with individual MAHs in developing multilingual labelling.

  A further mechanism utilised by the HPRA to aid continuity of supply to the market place in the event of a medicine shortage includes the granting of a temporary authorisation for a batch of a medicine known as a 'batch-specific request'. In 2019, there were 240 requests received.

- We continued to monitor the numbers of unauthorised products notified to us through the exempt medicinal product scheme. One aspect of our approach to reducing the risks to patients is to actively seek new marketing authorisation applications for high-volume products currently being imported through this scheme. Three such authorisations were issued in 2019.

Authorisation and registration: Key figures	2017	2018	2019
Classification queries / reviews	152	93	76
Scientific advice			
Lead in EMA scientific advice:	47	78	102
National scientific advice	6	10	20
Clinical trial applications	96	100	88
Voluntary Harmonisation Procedures (multinational clinical trials)			
Lead	5	1	2
Participating member state	14	22	8
New medicines applications for marketing authorisations			
National (including new parallel imports)	104	66	49
Mutual recognition and decentralised RMS	10	25	20
Mutual recognition and decentralised CMS	370	178	229
Centralised Rapp/Co-Rapp/Peer reviewer	12	19	17
Traditional herbal medicinal products under the simplified registration scheme	4	4	2
Homeopathic medicines under the simplified/national rules schemes	2	3	3
Variations to marketing authorisations (Type IA, IB, II)	11,600	10,077	14,957
Articles 45 and 46 - Variations to Update Product Information	2	1	0
Renewals of marketing authorisations	248	597	291
Transfer of marketing authorisation holder	208	801	1,583
Manufacturers	111	127	135
Manufacturers of investigational medicinal products	52	63	69
Wholesalers	348	358	385
Registrations for active pharmaceuticals ingredients			
Manufacturers	28	29	30
Importers	59	67	68
Distributors	81	87	92
Brokers	9	8	8
Export certificates	1,375	1,319	1,367
Exempt medicines programme for notification of unauthorised medicine import	1,961,541 packs	3,209,365 packs	2,586,120 packs

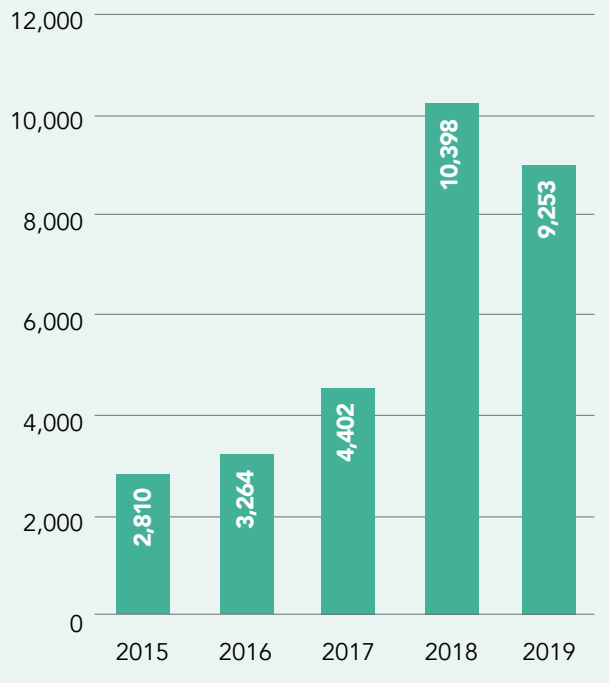
Safety and Quality

- Work continued in 2019 to manage the increased volume of reports and report reconciliation activities that that are a result of the introduction of changed reporting rules for the EU's EudraVigilance database of adverse reactions in late 2017.
- Adverse reactions reports assist the HPRA, in co-operation with pharmacovigilance professionals in Europe and further afield, to look for new types of reactions or changing trends in reporting. Reports submitted to the HPRA in many instances arise from concerns occurring during observation of an unexpected and / or unwanted event, in the context of use of a medicine. They also include known adverse reactions, such as those described in the product information.

This year:

– 9,253 adverse reaction reports were received associated with the use of human medicines. This represents an 11% decrease in overall reporting rates compared with 2018. This decrease was solely in cases received from MAHs via the Eudravigilance database managed by the EMA, and can be attributed to increased stability in the operation of the pharmacovigilance system in 2019 after the change to reporting rules in November 2017. Clarification around the respective reporting roles and a decrease in inappropriate and duplicate reporting contributed to the stabilisation, although the latter still remains an issue. Overall, there was a 19% increase in direct reporting to the HPRA from healthcare professionals and members of the public.

Adverse Reaction Reports



– Of the adverse reaction reports received by the HPRA in 2019, 90% were reported by MAHs, with a further 0.4% reported in the context of ongoing clinical trials. It is important to note that reports received by companies will have been initially notified to them by healthcare professionals, patients or consumers.

– Medicines subject to additional monitoring accounted for 22% of the reports submitted.

– The breakdown of reports submitted directly by members of the public and healthcare professionals was as follows:

Source of Report	%
Doctor	26%
Patient/Consumer	25%
Nurse	24%
Pharmacist	21%
Healthcare professional - Other	4%

– The medicines most frequently included in reports to the HPRA accounted for 81% of the adverse reaction reports received in 2019 (see table below). It is important to note that the place of a medicine on this list cannot be taken as an indicator of safety or risk. The number of reports received cannot be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using a medicine, is known.

Suspect Medicine(s) / Class of Medicines	Number of Reports*
Antineoplastics, including immunomodulating medicines, monoclonal antibodies and endocrine medicines	4,644
Psycholeptic medicines	547
Anti-infective medicines, including antibacterials, antimycotics, antivirals and immunoglobulins	429
Vaccines	374
Medicines for the treatment of Diabetes	365
Medicines for the treatment of Parkinson's disease	325
Medicines regulating parathyroid hormone levels	262
Cardiovascular medicines, including antihypertensive, anti-arrhythmic and lipid lowering medicines	207
Pituitary and hypothalamic hormones and analogues	197
Other nervous system medicines	189

* Please note that in some cases treatment may have involved more than one medicine from the groups listed.

– Of the new adverse reaction reports received by the HPRA in 2019, 159 patients were reported to have died while on treatment. The table (overleaf) outlines the medicines or class of medicines associated with the highest number of reports. In many of these cases, the patients had significant underlying illness and were treated with multiple medicines and/or surgery which may also have contributed to the outcome. In addition, many of these cases were influenced by disease progression or other complications unrelated to the medicine. The majority were associated with medicines subject to close monitoring, those used in the management of severe underlying medical conditions, in patient support programmes and special patient monitoring programmes.

Suspect Medicine(s) / Class of Medicines	Number of Reports*
Antineoplastics, including immunomodulating medicines, monoclonal antibodies and endocrine medicines	63
Psycholeptic medicines	33
Antithrombotic medicines, including anti-coagulant and anti-platelet medicines	18
Anti-infective medicines, including antibacterials, antimycotics, antivirals and immunoglobulins	7
Cardiovascular medicines, including antihypertensives, anti-arrhythmic and lipid lowering agents	6
Analgesic medicines	6
Systemic corticosteroid medicines	5
Medicines for the treatment of diabetes	4
Medicines for the treatment of depression	4
Medicines for the treatment of gastrointestinal conditions	4

* Please note that in some cases treatment may have involved more than one medicine from the groups listed.

- The HPRA also plays a key role in monitoring the safety of medicines on the Irish market via our vigilance assessment and risk management activities. This incorporates our contribution to the work of the Pharmacovigilance Risk Assessment Committee (PRAC) at the EMA. During 2019, the HPRA:
  - Continued our involvement in the work-sharing initiative for signal detection within the EU, acting as lead Member State for the monitoring of 70 nationally-authorised active substances. Serving as PRAC rapporteur, we were also responsible for the further management of any signals detected in relation to 55 centrally authorised medicines (containing 40 active substances / combination of active substances).
  - Participated in the EU periodic safety update report (PSUR) single assessment procedure, contributing to the evaluation of 763 PSURs and leading the single EU assessment for 41 of these procedures.
  - Participated as a concerned Member State in nine ongoing safety referrals, four of which reached a conclusion during the year.
  - Contributed to the review of 334 risk management plans (newly approved or updated) submitted via national, mutual recognition, decentralised and centralised procedures. We also provided assessment input to 633 post-authorisation safety procedures (safety study protocols, reports and other post authorisation safety-related measures).

- The HPRA continues to engage with multi-stakeholder groups, including patient and clinical practice representatives, to facilitate clinical readiness at national level for new recommendations on the safe and rational use of medicines following major EU benefit-risk reviews.

- Also during 2019, the HPRA commenced a research project, in collaboration with researchers from the RCSI, to assess the effectiveness of risk minimisation measures to prevent harms from teratogenic medicines. The project is funded through a Health Research Board Applied Partnership Award, which brings together the HPRA as knowledge user and the Royal College of Surgeons in Ireland as academic researcher.

- The inspections programme focuses on ensuring compliance with relevant standards and legislation. This year, there were:
  - 96 good manufacturing practice (GMP) inspections at sites that produce human medicines or active substances.
  - 135 good distribution practice (GDP) inspections at wholesalers and distributors;
  - Six good clinical practice inspections at investigator or sponsor sites;
  - Four pharmacovigilance inspections;
  - One bioanalytical inspection of a contract research organisation;
  - Four regulatory compliance inspections were conducted at the premises of marketing authorisation holders to determine the level of compliance with the legal requirements for the marketing and advertising of medicines.

- The risk-based sampling and analysis programme is part of our monitoring of the quality and safety of medicines on the Irish market or which are manufactured in Ireland for export. It involves the analytical testing of products and / or examination of their packaging and labelling. In 2019, 418 samples were taken under the programme. This included:
  - Examination of the packaging and labelling of 126 medicines and other products available on the Irish market. Twenty-four non-compliances were identified including Braille-related issues, non-compliant packaging and labelling, and the absence of updated safety information. Appropriate follow-up actions were taken in each case.
  - Analytical testing of 257 medicines and other samples of products for human use. With respect to non-enforcement samples, the majority were found to be compliant with their specifications. However, a number of out-of-specification results were also obtained. The most frequent of these related to nitrosamine impurity levels in sartan or ranitidine containing medicines being above the required limits. Again, appropriate follow-up actions were taken in each case.

- The quality defect and recall programme investigates, on a risk basis, reports of suspected quality defects in medicines and in their related active substances. It also co-ordinates recalls from the Irish market. Quality defects pertaining to 948 medicines for human use were reported or identified. The risk classifications that were assigned, along with the corresponding figures for the previous two years, are outlined in the accompanying table.

Classification	2017	2018	2019
Critical quality defects	124	325	259
Major quality defects	196	280	291
Minor quality defects	327	308	375
Number of reports not justified	3	12	23
Total Number Quality Defects	**650**	**925**	**948**

As in previous years, companies (47%), including manufacturers, distributors and/or authorisation holders, and other competent authorities (42%) were the primary sources of reports received.

- In certain cases, it may be deemed necessary to withdraw, or recall, medicines from the Irish market in order to protect public health. During the year, 125 medicine recalls occurred representing a 36% decrease when compared to 2018. Overall, the most common causes of recalls were:

Cause of Recall	Number of Recalls
Lack of sterility assurance	32
Contamination issues	29
Erroneous distribution activities	19
Stability issues	7
SPC / Printed artwork component issue	8
Non-compliance with specifications	5

- The HPRA monitors the sale of certain consumer health products in outlets such as grocery shops, health food shops and, where necessary, pharmacies. During 2019, 11 cases were investigated, some of which involved multiple products. Of these:
  - nine cases related to the sale of medicines that did not carry a valid registration number or authorisation number for the Irish market, resulting in 18 medicines being removed from sale and necessary follow-up actions being taken;
  - two cases related to the classification status of the products.

  In addition, 80 queries linked to the sale of health products in Ireland were addressed.

- The advertising compliance programme monitors and reviews advertising and promotion activities carried out by the industry in relation to human medicines for compliance with the legislation. In total, 414 advertisements were reviewed, and non-compliances, including both major and minor issues, were identified in 145 of these. In addition, one critical deficiency, two major deficiencies and several other (i.e. minor) deficiencies related to advertising activities were identified during inspections of marketing authorisation holders. In all cases, we oversaw the necessary corrective and/or preventative actions, where relevant. Seventeen complaints linked to the advertising of medicinal products were also received while 41 advertisements were recalled. A number of recalls were linked to complaints received.

- Under our enforcement programme:
  - The HPRA detained 1,018,678 dosage units (including tablets, capsules and vials) of falsified and other illegal medicines in 2019, compared to 619,213 units in 2018. The products detained included sedatives (34%), erectile dysfunction medicines (28%) and anabolic steroids (12%). There were 6,167 enforcement cases initiated, compared to 4,532 in the previous year;
  - Several HPRA operations took place in conjunction with An Garda Síochána and Revenue's Customs Service. These operations resulted in several large detentions, including the detention of over 60,000 capsules, tablets and vials labelled as anabolic steroids and destined for sale in the EU, and, in another investigation, 40,000 units of falsified diazepam tablets;
  - We initiated eight prosecution cases and issued nine voluntary formal cautions. Prosecutions are taken where the HPRA considers that there is a significant risk to public health or where there are persistent non-compliances. The prosecutions related to the unauthorised supply of prescription medicines, including falsified anabolic steroids, erectile dysfunction products and melanotan 2 (tanning injection) containing medicines. We also supported prosecutions brought by the Director of Public Prosecutions in relation to the illegal supply of medicines;
  - The Interpol-coordinated Operation Pangea XII was a year-long operation designed to enhance worldwide cooperation between health products regulators and other government agencies. The continued joint agency cooperation between the HPRA, Revenue's Customs Service and An Garda Síochána was reflected in the HPRA detention figures for 2019. In addition, the monitoring of websites, online marketplace advertisements and social media sites throughout the year resulted in the shutdown of 40 sites.

Legislation and Regulation

- The new Clinical Trial Legislation, Regulation EU No 536/2014, is provisionally planned to be implemented during 2021, when the development of the Clinical Trial Information System (CTIS) has been completed by the EMA.

  The following national activities were progressed during 2019:
  - We continued to engage with the Department of Health regarding the implementation of the Regulation and the development of national legislation;
  - We continued to offer a pilot project for simultaneous submission of applications to both the HPRA and ethics committee, which enables preparation for implementation of the Regulation. Guidance and templates for sponsors are available on our website;
  - We actively participated in the European voluntary harmonisation project, which is similar to the approval process for clinical trials under the planned new legislation (see page 17).

- Since 9 February 2019, under the Falsified Medicines Directive, the outer packs of prescription medicines must carry safety features in the form of an anti-tamper device and a barcode containing unique identifiers, including a serial number to allow verification of the authenticity of the packs. In 2019:
  - Preparations for the national implementation and introduction of these measures intensified. We worked with the Irish Medicines Verification Organisation (IMVO), which was responsible for establishing and managing the repository and software systems;
  - We contributed to a National Oversight Steering group of stakeholders which met regularly to monitor progress on implementation both nationally and across the EU;
  - The EU working group on supervision of the national repositories of unique identifiers, led by the HPRA, continued to work through its plan for the project.

Stakeholders and Partners

- In January, the HPRA's Chief Executive, Deputy Chief Executive and Director of Quality, Scientific Affairs and Communications, appeared before the Joint Committee on Health to address the implications of Brexit for the health sector. Following presentations from the Department of Health and the HSE, the HPRA responded to a number of queries linked to our regulatory role, with a particular focus on the potential impact of Brexit on medicines supply.

  In September, the HPRA appeared before the Committee once more to discuss the same topic. The HPRA's Chief Executive, Deputy Chief Executive and Scientific Affairs Manager attended again with representatives from the Department of Health and the HSE. On this occasion, the HPRA presented a detailed update on the extensive regulatory planning and stakeholder engagement that was intensifying in preparation for the potential worst-case scenario associated with a disorderly Brexit. The Committee was informed of the HPRA's commitment to protect the supply of medicines to Irish patients and healthcare professionals to the fullest extent possible, The HPRA also provided responses to a number of queries from the Committee members.

- As in recent years, the HPRA delivered a programme of presentations and talks at external stakeholder events such as meetings, seminars, conferences and training courses. Such presentations provide stakeholders such as healthcare professionals and regulatory professionals with access to relevant, up-to-date information. In addition, a programme of presentations was delivered to undergraduate and postgraduate students studying courses related to the role of the HPRA. A full list of all presentations delivered during 2019 relevant to human medicines is provided in Appendix 2.

- Publications and Information
  - The Drug Safety Newsletter provides important safety information to healthcare professionals with hyperlinks to product information and other relevant documents on the HPRA and EMA websites. Four issues of the newsletter were published and distributed to registered healthcare professionals, all of which are accessible from the HPRA website. A full index of topics covered during the past year is included in Appendix 3.
  - Risk communications:
    - During 2019, 112 new or updated educational materials were approved by the HPRA in addition to 28 direct healthcare professional communications.
    - The PRAC monthly agendas, minutes, meeting highlights, notifications of safety reviews and signals were also made available via our website.
  - There were 23 articles provided for inclusion in the monthly MIMS (Ireland) publication in addition to two articles for the Irish Medicines Formulary. The full list of topics covered in these articles is included in Appendix 3.
  - The Medicinal Products Newsletter provides regulatory news and updates for those working in the pharmaceutical industry. Three editions were published on our website in 2019 and are available to download from the 'Publications' section.
  - HPRA guidance documents provide stakeholders, primarily from the industry sectors we regulate, with advice and direction in respect of legislation and regulatory requirements. A number of existing guidance documents were updated during 2019 and are available to download from our website.

- HPRA information seminars and training events provide regulatory guidance and updates to a range of stakeholders. Our programme of events in 2019 included an information day on Brexit in February attended by over 300 delegates. We also hosted two significant international meetings linked to our enforcement activities. The first, organised in cooperation with Interpol over three days in March, considered Operation Pangea XI and combating the sale of illicit medicines online. The second, a weeklong event held at the end of May, was a meeting of Permanent Forum on International Pharmaceutical Crime (PFIPC). These two meetings together attracted more than 150 delegates.

Medical Devices

As the national competent authority for medical devices, the HPRA carries out a range of registration, surveillance, monitoring and compliance activities. Our aim is to ensure that these health products perform as intended and do not compromise the health and safety of the patient or the person using them.

Authorisation and Registration

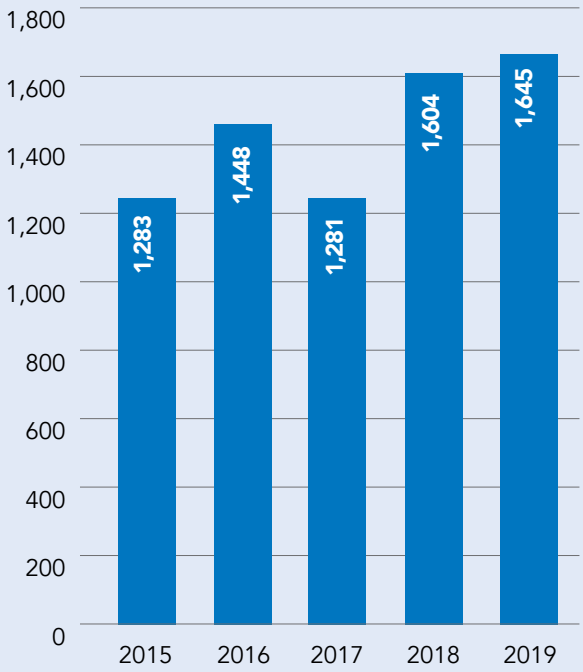
- The HPRA is focused on ensuring effective and consistent designation and oversight of notified bodies at national and European level. In 2019, we:
  - Assessed applications from organisations seeking to be designated as notified bodies in Ireland under the new EU Regulations on medical devices;
  - Continued our schedule of oversight of the notified body in Ireland based on ongoing assessment, surveillance and observed audits;
  - Provided expert assessors to participate in three EU joint assessments of notified bodies based in other European countries;
  - Continued to support development of EU coordination of notified body designation and oversight through participation in the EU Notified Body Operations Group (NBOG) and the Medical Device Coordination Group (MDCG).
- Supporting innovation and research of new technologies is a key strategic priority for the HPRA medical devices team. In 2019, this involved:
  - The review of applications to conduct clinical investigations of medical devices in Ireland. The number of clinical investigations decreased with five new applications and ten amendments to ongoing investigations. The HPRA anticipates that these numbers will increase when the new EU Regulations are implemented;
  - The HPRA continues to focus on this area to ensure regulatory requirements and processes are clear and accessible to potential applicants;
  - Encouraging engagement during product development and innovation of medical technologies. We met with 19 groups of innovators to discuss potential clinical investigation applications in 2019;
  - Supporting the work of the HPRA Innovation Office on medical devices queries received;
  - Presenting and participating in innovation sessions at a variety of conferences and workshops including the Euro PCR conference in Paris.

- Manufacturers of certain medical devices and *in-vitro* diagnostics are required to register with the HPRA. In 2019, the HPRA registered 99 new organisations manufacturing these products in Ireland. A total of 6,037 medical devices were also registered. This represented increased registrations when compared to previous years, some of which is attributable to the UK's exit from the European Union.

Safety and Quality

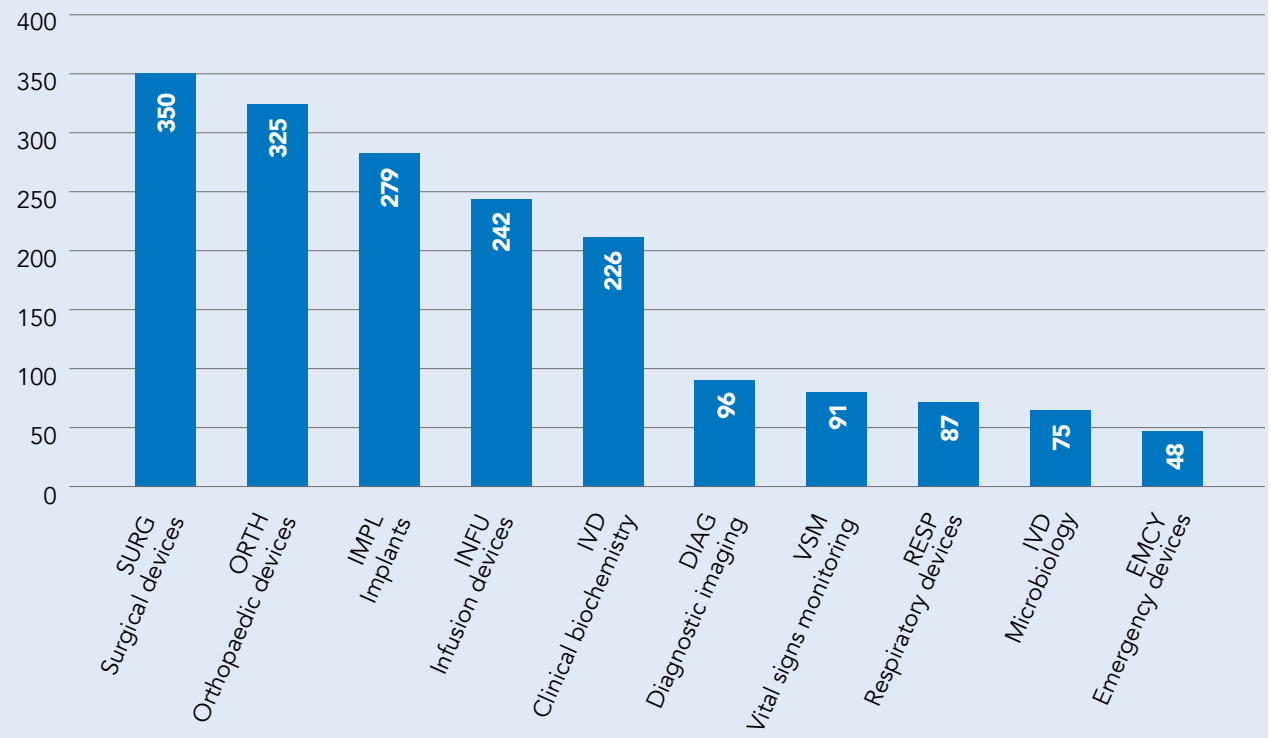
- We continue to develop and reinforce our market surveillance activities, with particular emphasis on proactive rather than reactive actions. Of note in 2019:
  - We utilised a lifecycle market surveillance strategy and planning mechanism to ensure continued safety and performance of devices throughout their lifetime;
  - We led or participated in various elements of both technical work packages of the EU Joint Action on Market Surveillance (JAMS) of medical devices initiative which is funded by the European Health Programme and aims to develop market surveillance activities;
  - A total of nine COEN notices were sent to the European network relating to medical device compliance concerns;
  - One information notice was published in relation to medical devices used during electrosurgery;
  - There were 1,645 market surveillance cases undertaken in 2019, a slight increase compared to 2018. Key areas of focus for market surveillance review included transvaginal mesh implant devices and breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

Market Surveillance Cases



- We continued to focus our vigilance activities during 2019 on the areas of user reporting and dissemination of HPRA medical device safety communications. This included:
  - The receipt and assessment of 2,295 medical device vigilance cases, similar to numbers received in 2018. Of the 1,105 incident reports notified to the HPRA, 13% came from users of medical devices. Manufacturers accounted for 60% of all reports received in 2019 while 32% came from other competent authorities;
  - There were 409 field safety corrective actions (FSCA) associated with the national market including 128 product removals conducted in Ireland during 2019;
  - We issued 84 national competent authority reports, eight notified body forms and four vigilance enquiry forms;
  - We also issued 33 safety notices in relation to medical device issues and 63 direct to healthcare professional communications;
  - Surgical devices, orthopaedic devices, implants and infusion devices accounted for 52% of the total vigilance reports. Reports continue to be received relating to in vitro diagnostic devices in the area of clinical biochemistry and medical devices in the areas of diagnostic imaging and vital signs monitoring. During the year, we also continued development work on signal detection of medical device issues.

Vigilance Reports Received – Top 10 Product Types



- As part of its market surveillance activities, the HPRA undertakes proactive and 'for-cause' audits of manufacturers, notified bodies and authorised representatives with the objective of monitoring compliance of devices emanating from Irish based organisations. During 2019, nine audits were performed at notified bodies, medical device manufacturers and authorised representative facilities, of which:
  - one was a for cause audit;
  - eight were based on proactive market surveillance projects and notified body surveillance/ assessment.

  In addition, there were three good distribution practice (GDP) inspections in respect of medical devices.

Legislation and Regulation

- The two new European Regulations on medical devices will become fully applicable in 2020. We continued our work during 2019 to help ensure an effective and timely implementation of these EU Device Regulations (EUDR) at national and European level. This included:
  - Implementing a HPRA programme plan for development of appropriate resources, process and systems to meet our obligations under the new EUDR;
  - Preparing detailed information relating to the new requirements with respect to the need for national legislation, the timelines and impact on existing national legislation;
  - Contributing to the European Commission's development of the secondary legislation involving implementing and delegating acts;
  - Participating in the new EU Medical Device Coordination Group (MDCG). Chaired by the EU Commission, this group is responsible for the overall coordination and governance of the regulatory system;
  - Participating in the EU Working Groups tasked with developing guidance for specific functional areas.

We continued to engage with the Department of Health throughout 2019 on policy and legislative issues arising from implementation of the new EU Regulations. At national level, we further developed our national fee-based funding model for medical devices to recover costs associated with our medical device activities. The model was revised in 2019 to streamline the approach and address some of the comments and feedback received following its initial introduction.

- The HPRA continues to play a significant role in the development of EU regulatory systems and mechanisms to promote co-ordination, co-operation and consistency. In 2019, this included:
  - Re-election to the Executive Group of the Competent Authorities for Medical Devices (CAMD) network. This group has successfully worked in partnership with the EU Commission over the last number of years to develop the regulatory system in Europe;
  - Participation in the CAMD's Implementation Task Force (ITF) and Transition Subgroup (TSG) which aim to improve co-ordination and consistency of implementation of the new EU Regulations and published guidance on what it means to be compliant by May 2020;
  - Continuing to lead the work of the clinical investigation and evaluation working group (CIEWG), acting as the co-chair along with the EU Commission.

- We continued to participate actively in initiatives to promote regulatory convergence and harmonisation of medical devices globally through the International Medical Device Regulators Forum (IMDRF). This involved:
  - Participation in the IMDRF Management Committee as part of the European delegation (along with the EU Commission, France and Germany);
  - Continuing to act as the IMDRF secretariat for the National Competent Authority Report (NCAR) Exchange programme. We also participated in a number of different IMDRF working groups including the group on Medical Device Single Audit Programme (MDSAP);
  - Contributing to discussions and development of the Medical Device Single Review Programme, which relates to product review;
  - Contributing to briefings for the EU Commission for the purposes of the MDSAP Regulatory Authority Committee discussions and also encouraging discussions at EU level to further Europe's future engagement in the programme.

Stakeholders and Partners

- Our work to further developing our stakeholder engagement and communication with medical devices stakeholders continued throughout 2019. This included the promotion of direct reporting of incidents and medical devices issues by device users and members of the public. We also continued our engagement with health services and healthcare professionals to encourage reporting and raise awareness of the roles and activities of the HPRA. We again promoted the adoption and communication of the HPRA step-by-step guide to user reporting which is targeted at healthcare providers.

- The HPRA undertook a number of communication initiatives to raise awareness of the impact and requirements arising from the new EUDR. During 2019, we:
  - Supported the TOPRA 2019 symposium on medical devices for manufacturers in Dublin. The event, which included a number of presentations from HPRA staff members, was attended by around 140 participants;
  - Continued to update the HPRA website and social media channels to provide information and guidance regarding EUDR;
  - Provided briefings, advice and workshops on the new Regulations to a range of different stakeholders including notified bodies and distributors.

- Throughout the year, we engaged in ongoing strategic, operational and communication initiatives on a bilateral and multilateral basis with European and international authorities, and the EU Commission. We also further developed our bilateral partnerships with a number of those authorities. In addition, we participated in operational and strategic discussions on developing cooperation between the CAMD and the Heads of Medicines Agencies (HMA) networks.

- The HPRA continues to deliver a programme of presentations and talks to a range of external stakeholders. A full list of all presentations related to the regulation of medical devices that were delivered during 2019 is provided in Appendix 2.

Medical devices: Key figures	2017	2018	2019
Lead Competent Authority role on specific vigilance issues	89	74	84
NCARs and vigilance related communications	96	111	118
Vigilance cases received/ opened	2,339	2,358	2,295
Field safety notices uploaded	519	475	461
Medical device safety notices	44	39	33
Medical device targeted healthcare professional communications	23	37	63
NCARs managed as IMDRF NCAR secretariat	8	8	8
COEN reports (market surveillance and vigilance) to EU network	44	38	9
Medical device information notices	5	2	1
Market surveillance cases (unadjusted)	411	353	263
Notifications relating to notified body certificates	844	1,174	1,305
Classification requests	51	37	45
Compassionate use applications	5	8	24
Medical device free sale certificates	2,371	2,581	2,710
Medical device queries received	496	547	857

Blood, Tissues and Organs

The HPRA is responsible for monitoring the safety and quality of blood and blood components and of tissues and cells. Along with the HSE, we are joint Competent Authority for organs intended for transplantation.

Authorisation and Registration

The authorisation of blood establishments, tissue establishments and organ procurement organisations / transplantation centres permits those facilities to carry out specified activities. The total number of authorisations in place at year-end for the past five years is presented by category in the accompanying table.

Number of Authorisations	2015	2016	2017	2018	2019
Blood establishments	3	3	3	3	3
Tissue establishments	24	25	25	26	27
Organ procurement/ transplantation	4	4	4	4	4

Safety and Quality

- Following collaboration with the National Haemovigilance Office (NHO), we submitted an annual report of serious adverse reactions and events to the EU Commission during 2019. The report reflected information received by the NHO in 2018 and included information on 46 serious adverse reactions and 128 serious adverse events that met the mandatory legislative reporting requirements.

- We also submitted an annual report on serious adverse reactions and events associated with tissues and cells to the EU Commission during 2019. The report reflected information received in 2018 and consisted of some 32 reports, 27 of which met the legislative reporting requirements, including three serious adverse reactions and 24 serious adverse events.

- Updates to the common approach for defining reportable serious adverse reactions and events and other vigilance activities in Europe are continuing under the SoHO Vigilance Expert Sub-Group (VES) at which the HPRA is actively participating. During 2019, the remit of this group was extended to include vigilance activities related to human organs for transplantation.

- We continued to liaise with the HSE lead and colleagues from Organ Donation and Transplant Ireland (ODTI) in relation to our respective roles under EU and national legislation on the Quality and Safety of Human Organs intended for Transplantation. During the past year, this included:
  - The exchange of relevant information on serious adverse reactions and events. In 2019, the HPRA received twelve reports of serious adverse reactions and events associated with organ donation / transplantation;
  - Updates to the organ report form;
  - Contribution to the review of the 'Framework for the Quality and Safety of Human Organs Intended for Transplantation'.

- We inspect relevant establishments, organisations and centres to monitor compliance with applicable national and EU legislation and guidelines on the quality and safety of blood, blood products, tissues and cells, and human organs intended for transplantation. Our inspection programme in 2019 included:
  - 24 tissue establishment inspections of which two were non-routine; and
  - Seven routine inspections of blood establishments.

Legislation and Regulation

- As part of our ongoing contribution to the preparation of relevant legislation, we provided feedback to the Department of Health on draft statutory instruments (SIs) for transposition of EU Directives on coding and import of human tissues and cells, which were signed early in the year, and on their implementation.

- In relation to assisted human reproduction, we engaged with the Department of Health on development of related legislation. We also continued to engage in respect of the commencement of parts 2 and 3 of the Children and Family Relationships Act 2015. A related Commencement Order was signed that will come into effect on 4 May 2020.

Veterinary Medicines

Our role is to grant licences for veterinary medicines subject to a review of their safety, quality and effectiveness. We continuously monitor the use of the products concerned in animals once they become available on the market in addition to authorising clinical field trials and inspecting / licensing manufacturing sites.

Authorisation and Registration

- There are a number of procedures through which a veterinary medicine can be authorised by the HPRA. These include the national procedure, the mutual recognition procedure (MRP) and the decentralised procedure (DCP). The following applications were issued by the HPRA during 2019:
  - Eleven new national applications;
  - 86 new applications made under the DCP;
  - Thirty new applications made under the MRP.

  We acted as reference (lead) Member State for the assessment of 13 of the MRPs and 38 of the DCPs. We also led a further nine applications as RMS under the repeat use procedure.

  The centralised route administered by the EMA is another mechanism whereby veterinary medicines can be authorised for supply in Ireland. HPRA experts acted as rapporteur or co-rapporteur in respect of 24 new veterinary medicines.

  Based on the figures presented above, the HPRA was the leading national competent authority in the EU for outgoing work during 2019.

  Additionally, by year-end, there was a record total of more than 1,850 veterinary medicines authorised in Ireland.

- During 2019, HPRA experts acted as co-ordinator (two) or joint co-ordinator (two) for four EMA scientific advice procedures.

- Concerning Brexit planning and preparation (see also pages 12 to 15), we focused on the HPRA's key strategic aim of protecting the availability of veterinary medicines on the Irish market while also optimising our role within the European regulatory network. During the past year, this included:
  - Changes to transfer procedures made to mitigate against Brexit related shortages. There was a total of 269 RMS transfers to Ireland;
  - Engagement with industry to identify potentially vulnerable products;
  - Recruitment and training of additional staff in response to anticipated increase in workload;
  - Discussion with the UK's Veterinary Medicines Directorate for a possible work-sharing arrangement post Brexit.

- Medicine shortages continue to be a challenge for many veterinary practitioners tasked with treating different species and conditions. Problems of non-

availability can arise from a number of issues and different solutions are needed depending on the issues involved. In 2019:

- We conducted planned quarterly reviews of AR18 and AR16 lists which provide details of veterinary medicines that have been granted special import licences by the Department of Agriculture, Food and the Marine. The HPRA strategy is to review the lists to identify required medicines and to encourage an applicant to seek a standard marketing authorisation where practicable;
- Carried out gap analysis and prioritised applications linked to shortages;
- Meetings were held with the Department of Agriculture, Food and the Marine to discuss shortages related issues including the need to develop an inter-departmental process in respect of potential shortages arising from Brexit;
- Communicated and met with applicants regarding transfer of RMS to Ireland. We also revised the relevant procedure and established a register of products for transfer;
- We worked closely with EU competent authorities to enable the use of common packs.

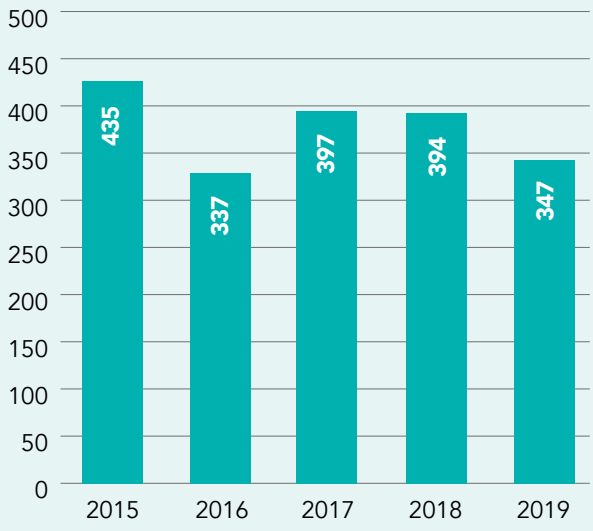
Authorisation and registration: Key figures	2017	2018	2019
Classification enquiries	11	26	12
Clinical trials	2	10	4
New centralised as (co-) rapporteur	16	3	24
New MR/DCP as RMS	30	34	38
New MR/DCP as CMS	44	57	48
New homeopathic applications	3	0	3
New national applications	8	11	6
Renewals, national and MR	108	148	87
Variations, national and MR	1,366	1,820	2,153
Manufacturers of veterinary medicines	20	23	24
Export certificates	111	109	125

Safety and Quality

- The operation of a national pharmacovigilance system for veterinary medicines is dependent on the submission of reports by veterinarians, pharmacists, licensed merchants and others involved in dispensing or using the medicines concerned. These reports may be submitted either directly to the HPRA or to the companies marketing the medicines. The companies, in turn, must relay the data to the HPRA.

  Over the course of 2019, we received 347 national reports of suspected adverse events to veterinary medicines with the vast majority of reports, as in previous years, received from pharmaceutical companies.

Adverse Event Reports



- We processed 1,189 periodic safety update reports (PSURs) which incorporated the assessment of individual medicines on the market in Ireland as well as a work-sharing initiative where we led, or contributed to, the assessment of a class of veterinary medicines for the European Union. .

- Containment of the development of antimicrobial resistance (AMR) is essential for public and animal health. Our work in this area includes the collection of annual information on the sale of veterinary antibiotics from each marketing authorisation holder. This information, which is included in the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC), is important as it allows us to benchmark our usage rate against those of our European neighbours and to follow any developing

trends. The data show that due to a variety of factors there are significant fluctuations in sales annually and, consequently, that a clear trend is not identifiable.

Veterinary antibiotic use	2014	2015	2016	2017	2018
Tonnes sold	89.4	96.9	103.4	99.7	99.4

Additionally in 2019, we collaborated with the Department of Agriculture, Food and the Marine to support the development of a database for antimicrobial consumption as per 'Ireland's National Action Plan on Antimicrobial Resistance 2017-2020'.

- The analytical testing of products is a key component of the HPRA's risk based sampling and analysis programme. Eight samples of veterinary medicines were taken under the programme and all were subjected to laboratory testing. In respect of all completed tests, samples were found to be compliant with their specifications.

- We investigate, on a risk basis, reports of suspected quality defects in medicines and active substances, and co-ordinate subsequent recalls from the Irish market where necessary. There were 68 quality defects pertaining to medicines for veterinary use reported or identified. The risk classifications that were assigned, along with the corresponding figures for the previous two years, are outlined in the accompanying table.

Classification	2017	2018	2019
Critical quality defects	5	26	10
Major quality defects	13	43	19
Minor quality defects	30	56	38
Number of reports not justified	0	0	1
Total Number Quality Defects	48	125	68

Companies (38%), including manufacturers, distributors and/or authorisation holders, and other competent authorities (62%) were the sources of the reports received.

In certain cases, in order to protect animal and/or public health, it is deemed necessary to withdraw, or recall, a veterinary medicine from the Irish market. Seven recalls of medicines occurred which was one more than in 2018. Of these, two were due to a lack of sterility assurance.

- Our inspections programme focuses on ensuring compliance with relevant standards and legislation. In 2019, there were 14 good manufacturing practice (GMP) inspections of sites that manufacture / test veterinary medicines.

Legislation and Regulation

- The new veterinary regulation came into effect on 28 January 2019 and will be applied from 2022. During 2019, we continued to meet and engage with the Department of Agriculture, Food and the Marine in respect of the preparations needed to support the new Regulation (Regulation 2019/6). In addition, we published an initial assessment of the impact of the medicines Regulation on veterinary practice in the Veterinary Ireland Journal. Planning in respect of the implications of the legislation on HPRA procedures is ongoing.

- We continued to monitor developments regarding the judicial review proceedings that contended that the labelling and packaging of veterinary medicines should be in both the Irish and English languages. It is noted that the matter has been referred to the European Court of Justice.

Stakeholders and Partners

- As part of our ongoing stakeholder engagement, in 2019 we:
  - Engaged in a consultation with stakeholders regarding the method of supply of antiparasitic veterinary medicinal products that are intended for food-producing animals, and produced a report on this topic;
  - Met with key interested parties (veterinary and farming organisations) to discuss availability issues and possible solutions.

- Throughout 2019, we continued our involvement across the EU regulatory network, which includes active participation at the EMA and the HMA.

- As in recent years, we delivered a programme of presentations to veterinarian students and veterinary nursing students on the role of the HPRA and the promotion of veterinary pharmacovigilance. We also presented at a number of industry stakeholder events. A full list of all presentations delivered during 2019 is provided in Appendix 2.

- Our Medicinal Products Newsletter provides updates for those working in the veterinary medicines sector on Irish and European legislation, new / revised HPRA regulatory publications and stakeholder events such as information days. Three editions were published on our website in 2019 and are available to download from the 'Publications' section.

- We also contributed a number of articles to the Veterinary Ireland Journal and the It's Your Field publication. Details are included in Appendix 3.

Scientific Animal Protection

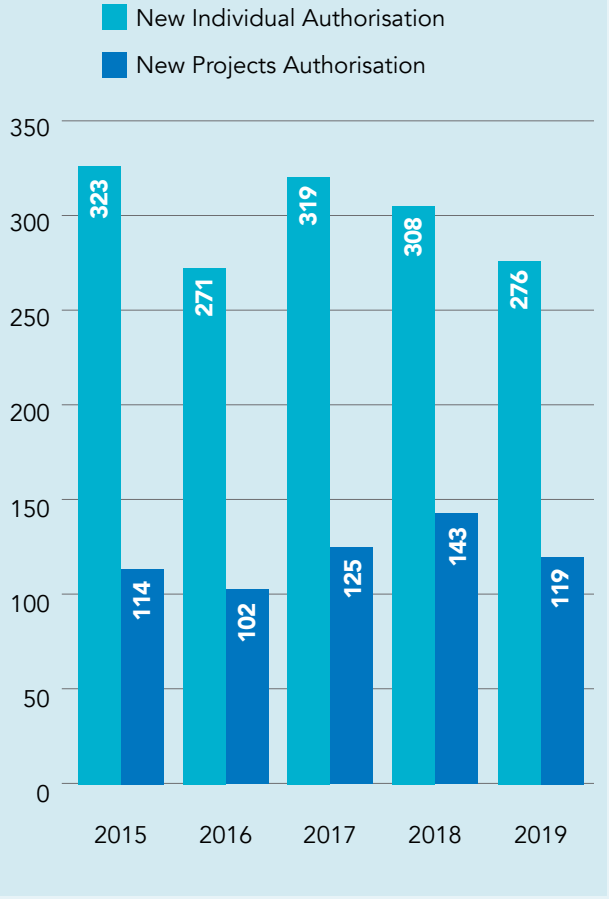
The HPRA is the competent authority in Ireland responsible for the implementation of EU legislation (Directive 2010/63/EU) for the protection of animals used for scientific purposes.

Authorisation and Registration

- The HPRA carries out evaluations of applications for the authorisation of research establishments and projects in addition to evaluating applications from individuals to allow them to manage projects or to conduct procedures or euthanasia of animals.

  As shown in the accompanying table, there was a decrease in the total number of projects authorised in 2019. In addition to the new individual authorisations issued during the year, there were also 111 renewals of individual authorisations.

Authorisations



- In June, we published the sixth annual statistical report on the use of animals for scientific purposes in Ireland. The HPRA is required to collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures.

Authorisation and registration	Key 2019 figures
Individual authorisations	276
Individual renewals	111
Project authorisation	119
Individual amendments	69
Project amendments	150
Establishment renewals	0

Safety and Quality

- During 2019, there were 31 inspections completed to monitor animal welfare standards and compliance with legislation, of which 32% were unannounced. This total incorporated one establishment authorisation inspection, one establishment renewal inspection and 29 compliance inspections.

  Of the 31 non-compliances recorded under the annual inspection programme, 26% were self-reported to the HPRA by personnel at the authorised establishment with the remainder detected on inspection or during other HPRA activities. Non-compliances are categorised as Type 1, Type 2 and Type 3, with Type 1 being the most serious and Type 3 being more minor in nature. In 2019, 6% of non-compliances were Type 1 (and these were all self-reported), 55% were Type 2 and 39% were Type 3. The most common non-compliances recorded related to (i) breaches of project authorisations, (ii) breaches of individual authorisations and (iii) issues with the control of relative humidity in animal holding rooms.

Stakeholders and Partners

- In 2019, we published and disseminated four 'Regulatory Updates' to provide stakeholders with the latest news and guidance from the HPRA including information on best practices in respect of the 3Rs and compliance with the legislation.

- We delivered a number of Laboratory Animal Science and Training (LAST) lectures in relation to the legislative and regulatory aspects of scientific animal protection. In June, we delivered a lecture at a meeting of the Irish designated veterinarians group, in relation to the responsibilities of the designated veterinarian under the scientific animal protection legislation.

Controlled Drugs and Precursor Chemicals

Authorisation and Registration

- Import, export and holding of controlled drugs (for legitimate purposes) are subject to licensing. The Department of Health is the licensing authority while the HPRA handles the administrative aspects of the application and licensing process. Licensing activity consists primarily of export and import licences, and letters of no objection. Data for the past five years are outlined in the accompanying graph.

Controlled Drugs Licensing Activity

- The HPRA is the licensing authority for precursor chemicals. These are subject to different licensing requirements, dependant on specific categories. The following table shows the licensing activity since 2015.

Precursor Chemicals Licensing Activity	2015	2016	2017	2018	2019
Total	32	16	23	23	13

- The HPRA processes, on behalf of the Department of Health, applications for licences to cultivate hemp. A cultivation licence is valid for a period of one year from the date it is granted. The below table shows the number of licences issued during the past four years.

Hemp Cultivation Licensing Activity	2016	2017	2018	2019
Total	7	16	24	74

Safety and Quality

- The HPRA carries out inspections of manufacturers and distributors of controlled drugs, as well as some other operators, as necessary, to monitor compliance with the relevant requirements. We conducted 19 inspections linked to the possession and/or supply of controlled drugs. Operators were informed of any non-compliances identified and requested to implement corrective actions.

Legislation and Regulation

- Throughout 2019, the HPRA provided support to the Department of Health in the establishment of the Medical Cannabis Access Programme. In June, Minister Harris signed the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019 (S.I No. 262 of 2019), the legislation required to underpin the programme. This allowed for commencement of the first stage, which was for potential suppliers to apply to have their cannabis products assessed for suitability for supply under the programme. Over the second half of 2019, a small number of applications from commercial suppliers seeking to have their products included were considered by the HPRA. From these applications, three cannabis products were considered to meet the specified requirements and were added to the programme.

  When the programme is fully operational, consultants on the specialist medical register will be able to prescribe a cannabis-based treatment for patients with any of three specified conditions:

  – Spasticity associated with multiple sclerosis resistant to all standard therapies and interventions;

  – Intractable nausea and vomiting associated with chemotherapy, despite the use of standard anti-emetic regimes;

  – Severe, refractory epilepsy that has failed to respond to standard anticonvulsant medications.

  Further information is available on the Department of Health website.

Stakeholders and Partners

- In June, we were invited to present at the Premier Irish Industrial Hemp Conference organised by GlasTeo and Teagasc on the application process for licences to cultivate hemp. The workshop was attended by external stakeholders with an interest in hemp cultivation.

Cosmetic Products

The role of the HPRA is to regulate the manufacture, sale and supply of cosmetic products in Ireland. We identify and address cosmetic product quality and safety issues, in conjunction with the HSE, so that a cosmetic product will not compromise the health and safety of the consumer or the person applying the product.

Authorisation and Registration

- We issued 165 cosmetics free sale certificates, which were requested by companies intending to export products to non-European Economic Area countries.

Safety and Quality

- As part of proactive market surveillance activities, we conducted one inspection of a cosmetic distributor and initiated one Product Information File (PIF) review to assess compliance with the Cosmetics Regulation. We informed distributors and manufacturers of any non-compliances identified and requested implementation of corrective actions.

- Our reactive market surveillance includes investigation of quality-related complaints (compliance cases), reports of adverse events relating to the use of cosmetics (vigilance cases) and serious risk alerts received from other countries (RAPEX). During 2019, 287 reactive surveillance cases were initiated.

Stakeholders and Partners

- In June, we were invited to present at the Irish Cosmetics, Detergent and Allied Products Association (ICDA) workshop: 'Potential Regulatory Impact of Brexit for Cosmetic and Detergent Companies'. The workshop was attended by Irish and UK cosmetics and detergent responsible persons, manufacturers and distributors.

- In June, we launched an information campaign to raise awareness amongst consumers regarding appropriate use of sunscreen products. The information was published as video content on our website and social media platforms. Consumers were informed of topics such as understanding sunscreen labels, the difference between UVA and UVB radiation and, how to apply and store sunscreens.

- In September, we hosted Cosmetic Product Regulatory Information evenings, in Galway and Dublin. Responsible persons, manufacturers and distributors of cosmetic products attended as well as representatives of potential start-up businesses. We provided information on their responsibilities under the Cosmetics Regulation, and on topical issues, including Brexit. A number of one-to-one meetings were also held with stakeholders to provide more specific information. Information packs and other HPRA publications relating to cosmetic products were also provided.

- In October, we hosted an information stand at the Taking Care of Business event in Athlone, which was attended by various stakeholders from SMEs and start-up businesses. We provided information on cosmetics regulation in general, as well as details of how the HPRA supports innovation and product development via our Innovation Office. Various HPRA publications relating to cosmetic products, innovation and medical devices were distributed.

Other Regulatory Programmes

Inspections, Audits and Market Compliance

- The Joint Audit Programme (JAP) is a key element of the quality system adopted by good manufacturing practice (GMP) inspectorates in Europe and aims to ensure consistency of GMP inspection standards and a harmonised approach throughout Europe. In 2019, the HPRA participated in the JAP evaluation of the GMP compliance programme of another member state.

- Other EU contributions included participation in / leading on:
  - the drafting group for the new EU GMP Guide Annex 21 on importation;
  - the development of a new risk assessment tool for the selection of medicinal products and active substances for surveillance testing;
  - a new risk-based tool to support inspection and surveillance relating to heparin manufacturers and their related products;
  - the development of a communication tool-kit for the Official Medicines Control Laboratory (OMCL) Network; and
  - the drafting group on development of an interpretation guideline on the JAP audit checklist.

Innovation Support

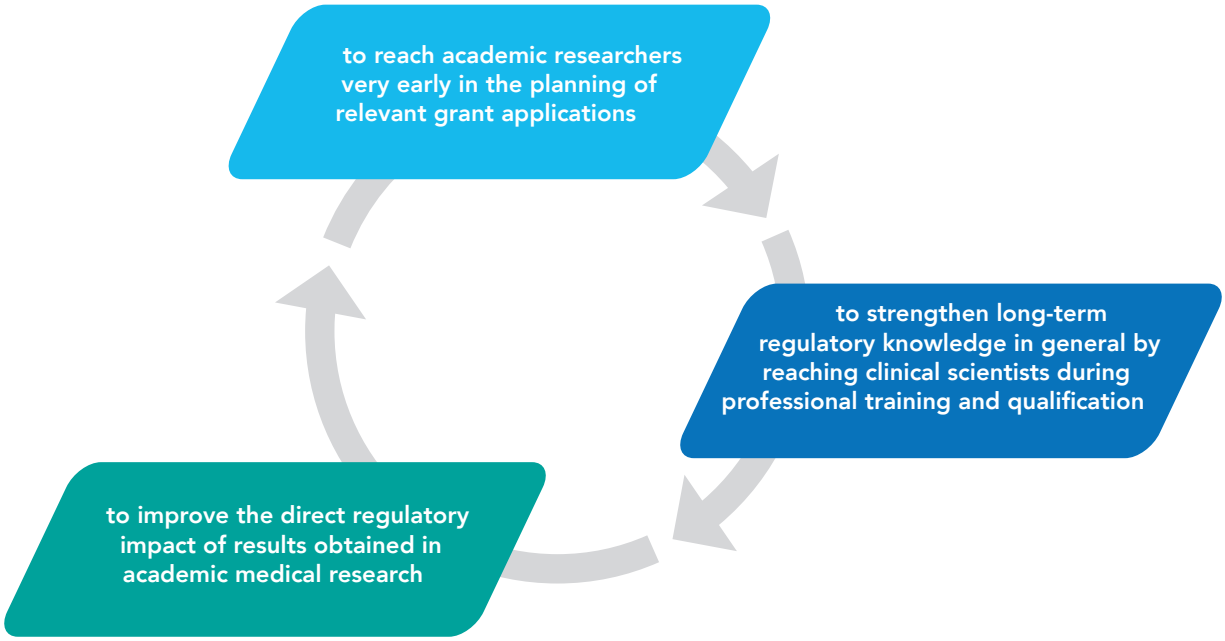
- The HPRA continues to focus on supporting innovation as one of our five strategic goals. This reflects our role not just to protect but also to enhance public and animal health. Our supports for innovation aim to facilitate safe and timely access to innovative health products and to increase and improve treatment options for patients. They also benefit the HPRA by helping to inform our future development and allowing us to identify novel product types and technologies that require new or adapted regulatory science approaches. Our actions to support innovation in 2019 included the following:
  - The HPRA's Innovation Office continues to offer regulatory support and advice to anyone developing an innovative health product or technology. Over 65% of the queries to Innovation Office originate from academia or small and medium enterprises who may have limited access to specialist regulatory advice. Medical devices was the most frequent area addressed through Innovation Office queries followed closely by medicines;
  - In 2019 the HPRA continued to take a lead role in the development of horizon scanning processes at a European level (within the EU Innovation Network) and at international level (within the International Coalition of Medicines Regulatory

Authorities (ICMRA). Horizon scanning is intended to identify novel health products at an early stage and inform the development of appropriate regulatory tools and approaches. This facilitates both effective regulation of such products and patient access;

– Throughout 2019, our classification process continued to offer advice to stakeholders on the borderline between different regulatory frameworks including medicines, medical devices, cosmetics and other products;

– The HPRA was part of a consortium of European medicines regulatory agencies who successfully applied to the European Commission for a Horizon 2020 funded coordination and support action. This project entitled 'Strengthening regulatory sciences and supporting regulatory scientific advice' (STARS) began in January 2019. The first year of this project has focussed on establishing the current level of regulatory knowledge among academic researchers via questionnaires that have been completed by research centres, funding agencies and regulatory authorities. The project aims are set out below.

STARS: Project Aims



Outreach and Engagement

The HPRA is committed to a strategic focus on outreach and engagement with key partners and stakeholders so as to enhance and maximise the effectiveness of the regulatory system.

- In our outreach activities to support innovation developments in Ireland:
  - The HPRA continued to meet and interact with a number of other state agencies and organisations who seek to support innovation in Ireland including the IDA, Enterprise Ireland, Health Innovation Hub Ireland and a number of third level institutions. We also met with individuals and organisations who are seeking to develop innovative health products and technologies to provide guidance on the regulatory requirements that will apply to their products.
  - The HPRA participated in a number of events around Ireland to promote our supports for innovation including the Taking Care of Business event organised by the Department of Business, Enterprise and Innovation in Athlone. In addition, reflecting our prominent role within the European network, the HPRA was invited to present on supports for innovation available from national competent authorities at the European Institute of Innovation and Technology (EIT) Health summit in Paris.
  - The HPRA continues to contribute to education programmes at both undergraduate and postgraduate levels. We also provided training placements to two 4th year pharmacy students as part of the five-year integrated pharmacist training programme.
- Stakeholder communications and engagement:
  - We continued our public information campaign: Zero Gains. The campaign is focused on building awareness of the many and often serious side effects associated with the non-medical use of anabolic steroids. The 2019 media plan, incorporating three bursts in January, June and September, was a mix of social and digital media in addition to outdoor and in-gym adverts. The website - **www.zerogains.ie** - continued to be an important element of the campaign providing reliable and trustworthy information on the real risks of anabolic steroid use. The 2019 campaign also incorporated new outdoor advertising sites (including in Dundrum shopping centre), the addition of Snapchat to our social advertising presence, and a sponsored article and digital insert on the thejournal.ie website. The campaign continued to perform in line with expectations with engagement levels typically at or in excess of industry norms.
  - Throughout the year, we continued our media communications programme to proactively communicate important safety messages and to build awareness of the role of the HPRA. We issued approximately 20 press releases and website statements concerning safety and regulatory matters to ensure consumers, healthcare professionals and other stakeholders

received timely and accurate information and advice. In a number of instances, these communications resulted in national and regional media interviews with a HPRA spokesperson. In addition, we responded to more than 370 initial and follow-up queries from national, local and specialist media during the year.

– The HPRA was pleased to participate again as one of a number of education partners working with the Irish Platform for Patient Organisations, Science & Industry (IPPOSI) to deliver the 2019 Patient Education Programme in the area of health innovation. The programme, which is specifically tailored for Irish patient communities, is based on a 'blended learning' approach consisting of e-learning and face-to-face sessions. The HPRA module was focused on regulatory affairs, medicines safety, pharmacovigilance and medical devices. Graduates of the programme, including both patients and patient advocates, are empowered to work effectively with Irish and EU-level health research and technology partners, agencies and authorities.

– The HPRA commenced work in 2019 on the establishment of our first ever patient forum. The objective of the forum, which will be established initially on a pilot basis and launch during 2020, is to improve two-way communication with patients so as to capture their views of the role and work of our organisation and the regulatory system. Identifying and acting upon patient perspectives has the potential to add real value to regulatory policies and decision-making. During 2019, we:

  ◦ Engaged with other health agencies and regulators, both nationally and at a European level, to identify best practices in this area;

  ◦ Developed a proposed forum structure / approach for the HPRA in addition to a draft role description for members;

  ◦ Issued a call for expressions of interest from potential members including graduates of the IPPOSI patient training programme and representatives from the patient associations representing the main disease areas in Ireland;

  ◦ Identified initial topics for discussion by the forum including patients' perspectives on the HPRA's nest five year Strategic Plan 2021-2025 and other topical issues such as Brexit and medicines shortages. Further topics will depend on areas of importance raised by members of the forum but will likely include the content, format and channels of communications between the HPRA and patients, and initiatives to help increase adverse reaction reporting rates.

  The response to the forum to date has been very positive among both organisations and perspective members and we look forward to its official launch in 2020.

– The HPRA website – www.hpra.ie – is a key communications channel and we continuously monitor and analyse key visitor and usage statistics. The key findings from 2019 included:

  ◦ More than 780,000 users of our website during the past twelve months representing a significant 44% increase compared to 2018.

  ◦ There were in excess of 4.4 million page views in total throughout the year, which is the highest annual number, recorded for our website.

  ◦ Of those who accessed the site, more than 47% were mobile phone users.

– The @TheHPRA Twitter account supports our communications activities and helps to direct additional traffic to the HPRA website. We continued to develop our Twitter activity during 2019 and by year end we had grown our number of followers by more than 41% to 2,550. Among the highlights was our continued participation in an international social media campaign to promote the reporting of suspected side effects from medicines. This campaign was supported by a range of patient organisations and other national health agencies.

– Our LinkedIn account continues to support the growth of our employer brand (see also page 47). In addition, it facilities the dissemination of important regulatory and safety information to health and industry professionals. By end 2019, our total number of followers had grown to 8,332.

– Also during 2019, we continued to utilise our corporate Instagram account to highlight and promote certain activities and events. The use of Instagram stories was again a key component of our Zero Gains anabolic steroids information campaign.

- European and international contribution:
  - Details of the extensive Brexit preparatory work carried out by the HPRA during 2019 are outlined on pages 12 to 15.
  - The HPRA continued to attend the quarterly EMA Management Board meetings:
    - At its October 2019 meeting, the Management Board elected HPRA Chief Executive, Dr Lorraine Nolan, as vice-chair of the Board for a three-year period. She has served as a member of EMA's Management Board, which is an integral governance body of the Agency, since March 2016. The Board has a supervisory role with general responsibility for budgetary and planning matters, the appointment of the Executive Director and the monitoring of the Agency's performance.
    - During 2019, the Management Board meetings were held in Amsterdam following the EMA's move from London in March. Initially, the Agency operated from temporary premises in Amsterdam Sloterdijk. Its newly built tailor-made premises, located in the Zuidas area of Amsterdam, was officially handed over to the EMA in November 2019. The subsequent move into the new EMA building in January 2020 marked the last step of the Agency's relocation to the Netherlands.
    - The coordination of Brexit related issues and oversight of activities linked to the relocation to new offices in Amsterdam were two items dominating the Management Board agenda throughout 2019. Other ongoing issues included the new veterinary legislation and clinical trials regulation implementation.
  - We continued our role as a member of the European Heads of Medicine Agencies (HMA) Management Group, which contributes to the direction and oversight of the HMA, following appointment in 2018. In addition to attending the quarterly HMA meetings, which took place in Timisoara and Bucharest in Romania and in Helsinki and Levi in Finland, we also participated as part of the secretariat for the monthly meetings of the HMA Brexit Task Force.
  - Additionally, as part of our ongoing contribution to the European regulatory system, HPRA scientific and technical staff participated in a broad range of committees and working parties at the European Commission, EMA, HMA, CAMD and other fora (see Appendix 4).
  - The HPRA continued to co-ordinate the International Coalition of Medicines Regulatory Authorities (ICMRA) innovation project as well as co-leading on a work stream with the EMA. We are also leading on the governance project, on a review of membership and on an update to the Terms of Reference. In addition, we assisted with the organisation of the ICMRA plenary meeting in San Diego by introducing and operating a registration and fee payment system.
  - The project to provide technical assistance to the Zambia Medicines Regulatory Authority was completed. Close out of the project was finalised and a confirmation letter of completion received from the PM Group.

- HPRA information events and training seminars provide regulatory guidance and updates to a range of stakeholders. The HPRA also partners with other regulatory organisations to co-host relevant events. During 2019, we hosted the following meetings:
  - Brexit Stakeholder Information Day – 1 February
  - Pangea XI and combating illicit online medicines – 12 to 14 March – Co-hosted with Interpol
  - Permanent Forum on International Pharmaceutical Crime – 27 to 31 May
  - Joint Action on Market Surveillance (medical devices) – 10 to 12 September
  - Cosmetic Products Information Evenings – 10 and 16 September in Galway and Dublin
  - Medical Devices Distributor Day – 13 November

- Also in 2019, the TOPRA Annual Symposium was held in Dublin from 30 September to 2 October in co-operation with the HPRA. The Symposium, which is recognised as a key event in the European regulatory affairs calendar, gives participants access to the latest information and insights directly from regulators, key opinion leaders and innovators. Of note:
  - The theme for the 2019 event was: "Europe at the forefront of global healthcare regulation: Driving innovation through convergent approaches in medicines, devices and veterinary regulatory affairs".
  - More than 640 participants attended from 31 countries representing over 300 entities, including 22 regulatory authorities.
  - Speakers included representatives from the World Health Organisation, the European Commission, the European Medicines Agency and various European national authorities. Attendees also heard from representatives of industry in addition to healthcare professional and patient groups.
  - HPRA staff members, as well as contributing to the planning for the event as part of the separate human medicines, veterinary medicines and medical devices symposium working parties, also delivered a broad range of presentations over the course of the three-day programme.

Key outreach and engagement figures 2019	**2019**
Public consultations held: - Proposed regulatory fees for human products - Proposed regulatory fees for veterinary medicines - Public consultation on HPRA Strategic Plan 2021-2025	3
Public consultations responded to: - Included Department of Health; Department of Business, Enterprise and Innovation; EMA; and PSI	13
Events managed by HPRA events teams	7
Freedom of information requests	33
Requests received in accordance with the Data Protection Acts	3
Parliamentary questions	52
Queries from Government departments or members of the Oireachtas	101
Protected disclosures received by external persons under section 7(2) of the protected Disclosures Act, of which investigation is: - Concluded - Ongoing	 6 3
Protected disclosures from HPRA staff members	0
Complaints	1
Customer service queries	3,336

Organisational Development

The HPRA is committed to having the necessary corporate functions, systems and supports in place to deliver on our public health mission. We must ensure that our organisational capabilities continue to expand and evolve in line with regulatory and scientific developments and that we adapt to other changes in our operating environment.

Human Resources and Change

Our HR and Change (HR&C) Strategy 2016 – 2020 continued to provide the framework for the development of our internal capabilities in the HPRA. The six core themes identified within the strategy drive our progress with various initiatives delivered throughout the year.

Highlights during 2019 include:

- Retention and Engagement:
  - Employee engagement pulse surveys continued with feedback and actions communicated at departmental level. Related support activities were undertaken.
  - The HPRA recognition programme was finalised and went live from Q4 with the first 'Accolade' award winners and the commencement of the celebration of service.
  - 2019 saw the rollout of our diversity and inclusion policy and related initiatives including a focus on Pride in June. We achieved the Investors in Diversity Award and a number of employees completed LGBT ally training.
  - The health and wellbeing agenda continued as a key focus with a number of activities held and the HPRA officially becoming a See Change partner. In addition, we received Marchathon Best Large Organisation and Top Coordinator awards, the Gold Active @ Work award from the Irish Heart foundation and successfully completed our interim review for the Keep Well Mark.
  - A review and edit of the LearningConnect web resource was completed to support a redesigned induction programme and to address needs identified in the 'Your Voice' employee engagement initiative.

- Career Development:
  - The cross-organisational working group continued the development of skill matrices for a number of roles and drafted changes to a new capability framework.
  - The second iteration of the graduate programme commenced in September 2019. Recruitment for the third iteration was also completed with graduate resources confirmed to commence in September 2020. A graduate blog series was also published via LinkedIn to support the promotion of the programme.

- HR and Change:
  - The new HR Business Partner model was finalised and launched in Q4.
  - Our social media presence was a key focus for our employer brand, achieved through targeted monthly planning of content, increased focus through recruitment campaigns and monitoring of analytics.
  - The HR&C department commenced ICAgile Accreditation in Q4 to implement an Agile HR methodology to support the organisation more effectively with increasing levels of complexity and change within our operating environment. Further training will be completed in Q1 2020 with a view to full accreditation being achieved in 2020.

- Organisation Design:
  - The restructure of the new Medical Devices department was completed with all related resourcing activities undertaken. The team competency matrix was finalised and training needs assessed. The project concluded successfully with development of the management team supported formally to assist during the transition period.
  - Support was provided in respect of the re-development and re-alignment of roles and responsibilities within the GMP Inspections team
  - Workshops, to examine re-alignment of some activities across the departments with human medicines responsibilities and to reduce handoff time and optimise processes, were facilitated and supported.

- Talent Management:
  - Preparatory activities were completed ahead of the successful go live of online recruitment via the HPRA Recruitment Portal in Q3 with a series of training videos and supporting instructional documentation drafted to facilitate the transition.
  - Recruitment activities saw an increase of 39% from 2018 to 2019 in terms of competitions completed which included additional headcount to support the additional Brexit related work.
  - Phase two of the MDP (management development programme) was completed while phase three commenced. Phase one of the LDP (leadership development programme) was also completed in addition to a needs analysis for the design of phase two.
  - The redesign of the new manager training programme was finalised and the first programme of our iLM accredited train the trainer (TTT) was completed.

- Change Management:
  - Support was provided for procurement and selection of an interim Senior ICT Manager, which included operational support for the team.
  - Supported work on researching and developing a remote working pilot.
  - Continued to provide representation and change management support in respect of the Eolas workflow system.
  - Provided of ongoing change management support to the project group implementing the new EU medical device Regulations.

IT Developments

- Enhancements continued to Eolas, the HPRA's workflow and data management system, which is a central platform to support its regulatory activities. The functionality of Eolas will continue to be enhanced and its footprint expanded to integrate other HPRA processes and procedures.
- A number of significant upgrades to additional systems were completed during the year giving added capability to users in support of their activities.
- Upgrades were made to the office and collaboration infrastructure including the introduction of Skype for Business and enhancements to the technology available in meeting rooms.
- There were 560,178 regulatory submissions made through the Common Electronic Submission Portal (CESP), which is managed by the HPRA on behalf of the wider EU regulatory community. By year-end, there were 6,578 organisations availing of CESP with over 23,766 individual users.

Quality Management

- The HPRA's quality management team was responsible for the continued implementation of policies and procedures relating to the General Data Protection Regulation (GDPR). There were three data subject requests received in 2019. All requests were managed within the required timelines.
- New guidance for stakeholders relating to the import/export licensing of cannabis products for medical use was published on the HPRA website.

Finance

- The HPRA is committed to the highest standards of corporate governance. During 2019, the financial statements for the previous year were prepared and submitted for audit to the Comptroller and Auditor General and subsequently published in the HPRA's 2018 Annual Report. All financial transactions during the period were reflected and reported upon in these statements.
- The annual review of regulatory fees for 2020, incorporating a public consultation, was completed followed by the publication of required fee changes.
- An internal audit review took place and a report was issued on income management.

Energy Usage

- The HPRA, as a public sector body, is required to report annually on its energy usage and actions taken to reduce consumption in accordance with the European Union (Energy Efficiency) Regulations 2014 (S.I. No. 426 of 2014). As an organisation, we use electricity for lighting, air conditioning or heating as required and the provision of hot water; natural gas is used for central heating. In 2019, the HPRA consumed 718.2 MWh* of energy consisting of:

  – 499.7 MWh of electricity

  – 218.5 MWh of fossil fuels

  – 0 MWh of renewable fuels.

  Total energy reduction at year end was 38.6%, exceeding the goal of 33% by 2020 (as calculated and published by the Sustainable Energy Authority of Ireland (SEAI).

  * published by the SEAI

Authority and Committees

- The Authority of the HPRA met six times in 2019 and considered a number of strategic matters including preparations for Brexit, corporate policy, planning, and financial matters. The latter included monthly management accounts, annual budgets and the financial statements for 2018. The Authority also reviewed update reports from the Statutory Advisory Committees and the Audit and Risk Committee. In addition, it reviewed the licences for all medicinal healthcare products as approved by the Management Committee.

  The number of meetings attended by each Authority member during 2019 was as follows:

Authority Member	Number of meetings held during the period the member was on the Authority	Number of meetings attended during the period the member was on the Authority
Ms. Ann Horan (Chairperson)	6	6
Mr. Pat Brangan	6	6
Mr. Wilf Higgins	6	6
Mr. David Holohan	6	6
Mr. Brian Jones	6	4
Dr. Elizabeth Keane	6	6
Prof. David Kerins	4	2
Prof. Caitriona O'Driscoll	6	6
Dr. Diarmuid Quinlan	6	4

  - The Audit and Risk Committee, a subcommittee to the Authority, met four times in 2019. Further details are provided in the HPRA's Financial Statements.
  - The Advisory Committee for Human Medicines met on two occasions in 2019. The Clinical Trials Sub-Committee is a sub-committee to the Advisory Committee for Human Medicines and it met twelve times in the past year.
  - The Advisory Committee for Veterinary Medicines met twice as did the Advisory Committee for Medical Devices.
  - The National Committee for the Protection of Animals Used for Scientific Purposes, a statutory committee to provide guidance to the regulator and those working in this area, met twice in 2019.

- Decisions of the Authority:

  The terms of reference of the Authority, which are published on the HPRA website, include an overview of how the Authority operates, an overview of all decisions taken by the Authority and those devolved to the Management Committee.

  The following decisions are reserved functions of the Authority:

  - The Authority takes decisions relating to very significant and serious public and/or animal health matters except in circumstances where a meeting of the Authority cannot be convened, in which case the Management Committee takes the decision and informs the Chairperson at the earliest opportunity and the Authority as soon as is practical.

– The Authority refuses applications, or suspends, revokes or terminates authorisations as set out in legislation except in circumstances where:

  (a) the urgency is such that a meeting of the Authority cannot be convened, or

  (b) the application or authorisation is subject to a binding European decision, or

  (c) the application or authorisation is for a clinical trial or clinical investigation; in which case the Management Committee takes the decision and informs the Authority.

– Through its Audit Committee, the Authority approves the internal financial controls and the financial audit function and satisfies itself that the financial controls and systems of risk management are robust and defensible. The Authority appoints the internal financial auditor.

- The Authority approves the investment policy, major investments, capital projects and the terms of major contracts.

- Significant acquisitions and the disposal or retirement of assets above a threshold set by the Authority are subject to Authority approval.

- The Authority approves treasury policy and risk management policies.

- The Authority approves corporate plans as required.

- The Authority approves the annual budget, monitors expenditure and supervises the preparation and submission of the annual statutory accounts.

- The Authority makes an annual report on the activities of the HPRA, including a financial statement, to the Minister for Health. This report is then published.

- The Authority selects and appoints the Chief Executive, with the consent of the Minister for Health. The terms of office and the remuneration of the Chief Executive are determined by the Minister for Health, after consultation with the Authority and with the consent of the Minister for Finance. The Authority, through its Performance Review Committee, conducts a process of annual performance appraisal of the Chief Executive. Succession planning for the role of Chief Executive is also undertaken by the Authority.

Financial Statements

for the Year Ended 31 December 2019

Authority Members and Other Information

Authority:	*Most recent appointment date*	*Expiry date*
Ms. Ann Horan (Chairperson)	01/01/2016	31/12/2020
Mr. Pat Brangan	22/05/2017	31/12/2019
Mr. Wilfrid Higgins	22/05/2017	31/12/2019
Mr. David Holohan	27/01/2016	26/01/2021
Mr. Brian Jones	27/01/2016	26/01/2021
Dr. Elizabeth Keane	22/05/2019	21/05/2022
Prof. David Kerins	22/03/2019	31/12/2020
Prof. Caitriona O'Driscoll	01/01/2016	31/12/2020
Prof. Richard Reilly	01/01/2020	31/12/2024
Dr. Diarmuid Quinlan	22/05/2019	21/05/2024

All Authority members are appointed by the Minister for Health.

Bankers:

Allied Irish Bank
1-3 Lower Baggot Street
Dublin 2

Bank of Ireland Corporate
2 Burlington Plaza
Burlington Road
Dublin 4

KBC Bank Ireland
Sandwith Street
Dublin 2

Solicitors:

Eugene F. Collins
Temple Chambers
3 Burlington Road
Dublin 4

Eversheds
1 Earlsfort Centre
Earlsfort Terrace
Dublin 2

Byrne Wallace
88 Harcourt Street
Dublin 2

Head Office:

Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Auditors:

Comptroller and Auditor General
3A Mayor Street Upper
Dublin 1

Governance Statement and Authority Member's Report

Governance

The Health Products Regulatory Authority (the HPRA) was established under the terms of the Irish Medicines Board Act, 1995 (as amended), and is governed by an Authority which was appointed by the Minister for Health. The Authority of the HPRA (the Authority) consists of a chairperson and eight non-executive members. The Authority is accountable to the Minister for Health and is responsible for ensuring good governance, and performs this task by setting strategic objectives and targets and taking strategic decisions on all key business issues. The regular day-to-day management, control and direction of the HPRA are the responsibility of the Chief Executive and the Management Committee. The Chief Executive and the Management Committee must follow the broad strategic direction set by the Authority, and must ensure that all Authority members have a clear understanding of the key activities and decisions related to the HPRA, and of any significant risks likely to arise. The Chief Executive acts as a direct liaison between the Authority and management of the HPRA.

On 1 July 2014 the organisation changed its name from the Irish Medicines Board, as provided for in Section 36 of the Health (Pricing and Supply of Medical Goods) Act 2013 and SI (205/2014) Health (Pricing and Supply of Medical Goods) Act 2013 (Commencement) order 2014.

Authority Responsibilities

The work and responsibilities of the Authority are set out in the Irish Medicines Board Act, 1995 (as amended), as well as in the 'Terms of Reference and Rules of Procedure' of the HPRA, which also contains the matters specifically reserved for Authority decision. Standing items considered by the Authority include:

- declaration of interests,
- reports from committees,
- financial reports / management accounts,
- performance reports, and
- reserved matters.

The Authority is required by the Irish Medicines Board Act, 1995 to prepare financial statements for each financial year which give a true and fair view of the financial position of the HPRA and of its surplus or deficit for that period.

In preparing those statements the Authority is required to:

- select suitable accounting policies and apply them consistently,
- make judgements and estimates that are reasonable and prudent,
- prepare the financial statements on a going concern basis unless it is inappropriate to presume that the HPRA will continue in existence, and
- state whether applicable accounting standards have been followed, subject to any material departures disclosed and explained in the financial statements.

The Authority is responsible for keeping adequate accounting records which disclose, with reasonable accuracy at any time, the financial position of the HPRA and which enable it to ensure that the financial statements comply with the Irish Medicines Board Act, with accounting standards generally accepted in Ireland and with accounting directions issued by the Minister for Health. The maintenance and integrity of the corporate and financial information on the HPRA's website is the responsibility of the Authority.

The Authority is responsible for approving the annual plan and budget. It is also responsible for safeguarding the assets of the HPRA and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The Authority considers that, except for the non-compliance with the requirements of FRS102 in relation to retirement benefits, the financial statements of the HPRA give a true and fair view of the financial performance and the financial position of the HPRA at 31 December 2019.

Audit and Risk Committee

The HPRA has an audit and risk committee comprising three Authority members, which met on 4 occasions during 2019. This committee is responsible for reviewing internal control matters, together with any other issues raised by the external auditors, the Authority or management. The external auditor is invited annually to meet with the audit and risk committee to brief them on the outcome of the external audit, and the audit and risk committee also meets annually with the internal auditor. During 2019 the internal auditor carried out an internal audit review on the area of income management. The audit and risk committee has also been involved with the review of the quality systems as described below.

Quality Systems

During 2019, the finance section of the HPRA continued the process of implementing and reviewing standard operating procedures (SOPs) under the quality management system. This process involved a critical review and analysis of internal controls and processes throughout the section with particular emphasis on risk management. This system now underpins the internal control environment and feeds into the internal audit process and ultimately into the audit and risk committee.

Remuneration Policy – Authority Members and Executive Directors

Remuneration and travel expenses paid to Authority members are disclosed in note 17 to the Financial Statements. The Chairperson receives remuneration as directed by the Minister for Health in accordance with the Irish Medicines Board Act, 1995. Other Authority members receive remuneration under the terms of the Health (Miscellaneous Provisions) Act 2017. All Authority members are entitled to receive travel expenses in accordance with circulars issued by the Department of Health. The Chief Executive is remunerated in accordance with guidelines issued from Government and other Executive Directors are paid in accordance with Department of Health pay scales. The remuneration of the Chief Executive and Executive Directors are disclosed in note 18 to the Financial Statements.

Internal Control

The Authority is responsible for the HPRA's systems of internal control. Such systems can only provide reasonable and not absolute assurance against material misstatement or loss. The systems of internal controls in use in the HPRA are described more fully in the Chairperson's report on pages 54 to 55.

Disclosures Required by Code of Practice for the Governance of State Bodies (2016)

The Authority is responsible for ensuring that the HPRA has complied with the requirements of the Code of Practice for the Governance of State Bodies, as published by the Department of Public Expenditure and Reform in August 2016. The following disclosures are required by the Code, and are contained in the notes to the financial statements:

- employee short term benefits breakdown,
- consultancy costs,
- legal costs and settlements,
- travel and subsistence expenditure, and
- hospitality expenditure.

Statement of Compliance

The Authority has adopted the Code of Practice for the Governance of State Bodies (2016) and has put procedures in place to ensure compliance with the Code. The HPRA was in full compliance with the Code of Practice for the Governance of State Bodies for 2019.

Performance Review

The Authority carried out a self-assessment evaluation of its own performance and its committees during the year ended 31 December 2019.

On behalf of the Authority

Ms. Ann Horan
Chairperson

Mr. David Holohan
Authority Member

Date: 18 June 2020

Statement on Internal Control

Scope of Responsibility

I, as Chairperson, acknowledge the Authority's responsibility for ensuring that an effective system of internal control is maintained and operated. This responsibility takes account of the requirements of the Code of Practice for the Governance of State Bodies (2016).

Purpose of the System of Internal Control

The system of internal control is designed to manage risk to a tolerable level rather than to eliminate it. The system can therefore only provide reasonable and not absolute assurance that assets are safeguarded, transactions authorised and properly recorded and that material errors or irregularities are either prevented or detected in a timely way.

The system of internal control, which accords with guidance issued by the Department of Public Expenditure and Reform, has been in place in the HPRA for the year ended 31 December 2019 and up to the date of approval of the financial statements.

Capacity to Handle Risk

The HPRA has an audit and risk committee comprising three Authority members, which met on 4 occasions during 2019.

The HPRA has outsourced the internal audit function to an independent professional firm, who conduct a programme of work as agreed with the audit and risk committee. During 2019 one internal audit review was conducted.

The HPRA have developed a risk management framework, which sets out its risk appetite, the risk management processes in place and details the roles and responsibilities of staff in relation to risk. This framework has been made available to all staff, who are expected to work within the HPRA's risk management policies, to alert management on emerging risks and control weaknesses, and assume responsibility for risks and controls within their own area of work.

Risk and Control Framework

The HPRA has implemented a risk management system which identifies and reports key risks and the management actions being taken to address, and to the extent possible, to mitigate those risks.

A risk register is in place which identifies the key risks facing the HPRA, and these have been identified, evaluated and graded according to their significance. The register is reviewed and updated by management, considered by the audit and risk committee twice per year and presented to the Authority. The outcome of these assessments is used to plan and allocate resources to ensure risks are managed to an acceptable level.

The risk register details the controls and actions needed to mitigate risks and responsibility for operation of controls assigned to specific staff. I confirm that a control environment containing the following elements is in place:

- procedures for all key business processes have been documented,
- financial responsibilities have been assigned at management level with corresponding accountability,
- there is an appropriate budgeting system with an annual budget, which is kept under review by senior management,
- there are systems aimed at ensuring the security of the information and communication technology systems, and
- there are systems in place to safeguard the assets.

Ongoing Monitoring and Review

Formal procedures have been established for monitoring control processes, and any control deficiencies are communicated to those responsible for taking corrective action, and to management and the Authority, where relevant, in a timely manner.
I confirm that the following ongoing monitoring systems are in place:

- key risks and related controls have been identified, and processes have been put in place to monitor the operation of those key controls and report any identified deficiencies,
- reporting arrangements have been established at all levels where responsibility for financial management has been assigned, and
- there are regular reviews by senior management of periodic and annual performance and financial reports, which indicate performance against budgets.

Procurement

I confirm that the HPRA has procedures in place to ensure compliance with current procurement rules and guidelines, and that during 2019 the HPRA complied with those procedures, with the following exception.

In 2019 the HPRA incurred €117K of telecommunications expenditure on foot of documented business justifications and memos from senior management. The expenditure was incurred on four contracts which were rolled over due to overriding business priorities, while also waiting on the results of the unified communications project, together with the findings of the HPRA digital transformation strategy. This project is expected to be completed during 2020, when this expenditure will be subject to a procurement tender process.

Review of Effectiveness

I confirm that the HPRA has procedures to monitor the effectiveness of its risk management and control procedures. The HPRA's monitoring and review of the effectiveness of the system of internal control is informed by the work of the internal and external auditors, the audit and risk committee which oversees their work, and the senior management within the HPRA, responsible for the development and maintenance of the internal control framework.

I confirm that the Authority conducted an annual review of the effectiveness of the internal controls for 2019. This review was carried out at its meeting on 3 March 2020.

Internal Control Issues

No weaknesses in internal control other than the one outlined above were identified in relation to 2019 that require disclosure in the financial statements.

Ms. Ann Horan
Chairperson to the Authority

Date: 18 June 2020

Comptroller and Auditor General

Report for presentation to the Houses of the Oireachtas

Qualified opinion on financial statements

I have audited the financial statements of the Health Products Regulatory Authority (the Authority) for the year ended 31 December 2019 as required under the provisions of section 18 of the Irish Medicines Board Act, 1995. The financial statements have been prepared in accordance with Financial Reporting Standard (FRS) 102 – *The Financial Reporting Standard applicable in the UK and the Republic of Ireland* and comprise

- The statement of income and expenditure and retained revenue reserves
- The statement of financial position
- The statement of cash flows and
- The related notes, including a summary of significant accounting policies.

In my opinion, except for the non-compliance with the requirements of FRS 102 in relation to retirement benefit entitlements referred to below, the financial statements give a true and fair view of the assets, liabilities and financial position of the Authority at 31 December 2019 and of its income and expenditure for 2019 in accordance with FRS 102.

Basis for qualified opinion on financial statements

In compliance with the directions of the Minister for Health, the Authority accounts for the costs of retirement benefit entitlements only as they become payable. This does not comply with FRS 102 which requires that the financial statements recognise the full cost of retirement benefit entitlements earned in the period and the accrued liability at the reporting date. The effect of the non-compliance on the Authority's financial statements for 2019 has not been quantified.

I conducted my audit of the financial statements in accordance with the International Standards on Auditing (ISAs) as promulgated by the International Organisation of Supreme Audit Institutions. My responsibilities under those standards are described in the appendix to this report. I am independent of the Authority and have fulfilled my other ethical responsibilities in accordance with the standards.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Report on information other than the financial statements, and on other matters

The Authority has presented certain other information together with the financial statements. This comprises the annual report, the governance statement and Authority members' report and the statement on internal control. My responsibilities to report in relation to such information, and on certain other matters upon which I report by exception, are described in the appendix to this report.

I have nothing to report in that regard.

Andrew Harkness

For and on behalf of the Comptroller and Auditor General

25 June 2020

Appendix to the report

Responsibilities of Authority Members

As detailed in the governance statement and Authority members' report, the Authority members are responsible for

- The preparation of financial statements in the form prescribed under section 18 of the Irish Medicines Board Act 1995
- Ensuring that the financial statements give a true and fair view in accordance with FRS 102
- Ensuring the regularity of transactions
- Assessing whether the use of the going concern basis of accounting is appropriate, and
- Such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

Responsibilities of the Comptroller and Auditor General

I am required under section 18 of the Irish Medicines Board Act 1995 to audit the financial statements of the Authority and to report thereon to the Houses of the Oireachtas.

My objective in carrying out the audit is to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement due to fraud or error. Reasonable assurance is a high level of assurance, but it is not a guarantee that an audit conducted in accordance with the ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with the ISAs, I exercise professional judgement and maintain professional scepticism throughout the audit. In doing so,

- I identify and assess the risks of material misstatement of the financial statements whether due to fraud or error; design and perform audit procedures responsive to those risks; and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- I obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal controls.
- I evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures.
- I conclude on the appropriateness of the use of the going concern basis of accounting and, based on the audit evidence obtained, on whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Authority's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my report. However, future events or conditions may cause the Authority to cease to continue as a going concern.
- I evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

I communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that I identify during my audit.

Information other than the financial statements

My opinion on the financial statements does not cover the other information presented with those statements, and I do not express any form of assurance conclusion thereon.

In connection with my audit of the financial statements, I am required under the ISAs to read the other information presented and, in doing so, consider whether the other information is materially inconsistent with the financial statements or with knowledge obtained during the audit, or if it otherwise appears to be materially misstated. If, based on the work I have performed, I conclude that there is a material misstatement of this other information, I am required to report that fact.

Reporting on other matters

My audit is conducted by reference to the special considerations which attach to State bodies in relation to their management and operation. I report if I identify material matters relating to the manner in which public business has been conducted.

I seek to obtain evidence about the regularity of financial transactions in the course of audit. I report if I identify any material instance where public money has not been applied for the purposes intended or where transactions did not conform to the authorities governing them.

I also report by exception if, in my opinion,

- I have not received all the information and explanations I required for my audit, or
- The accounting records were not sufficient to permit the financial statements to be readily and properly audited, or
- The financial statements are not in agreement with the accounting records.

Statement of Income and Expenditure and Retained Revenue Reserves
For the year ended 31 December 2019

	Note	2019 €	2018 €
Fee Income	3	**27,932,876**	23,901,603
Department of Health Funding	3	**4,964,255**	4,316,000
Other Income	4	**805,824**	888,884
		33,702,955	29,106,487
Salaries and Wages	5	**23,862,438**	21,160,214
Other Operating Costs	6	**7,639,373**	5,885,565
Depreciation	2	**1,274,848**	1,593,390
		32,776,659	28,639,169
Surplus for the year before write back of Superannuation contributions		**926,296**	467,318
Staff Superannuation Contributions		**691,855**	696,116
Surplus for the year		**1,618,151**	1,163,434
Balance brought forward		**29,488,113**	28,324,679
Balance carried forward	12	**31,106,264**	29,488,113

The Statement of Income and Expenditure and Retained Revenue Reserves includes all gains and losses recognised in the year. The Statement of Cash Flows and the notes on pages 62 to 72 form part of the financial statements.

On behalf of the Authority

Ms. Ann Horan
Chairperson

Mr. David Holohan
Authority Member

Date: 18 June 2020

Statement of Financial Position
As at 31 December 2019

	Note	2019 €	2018 €
Fixed Assets			
Property, Plant and Equipment	2	**24,896,454**	24,427,830
Current Assets			
Debtors and Prepayments	7	**2,514,984**	2,198,340
Inventory of Stationery		**5,533**	3,498
Cash and Cash Equivalents	9	**2,290,820**	10,162,555
Short Term Deposits	10	**17,658,240**	8,216,814
		22,469,577	20,581,207
Current Liabilities - Amounts falling due within one year			
Creditors and Accruals	8	**12,293,087**	10,760,912
Mortgage	13	**793,332**	793,332
		13,086,419	11,554,244
Net Current Assets		**9,383,158**	9,026,963
Long Term Liabilities - Amounts falling due after more than one year			
Mortgage	13	**3,173,348**	3,966,680
NET ASSETS		**31,106,264**	29,488,113
Reserves			
Retained Revenue Reserves	12	**31,106,264**	29,488,113
		31,106,264	29,488,113

The Statement of Cash Flows and the notes on pages 62 to 72 form part of the financial statements.

On behalf of the Authority

Ms. Ann Horan
Chairperson

Mr. David Holohan
Authority Member

Date: 18 June 2020

Statement of Cash Flows
For the year ended 31 December 2019

	Note	2019	2018
		€	€
Cash flows from Operating Activities			
Surplus for financial year		1,618,151	1,163,434
Depreciation of property, plant and equipment		1,274,848	1,593,390
(Profit)/Loss on Disposal of property, plant and equipment		(49)	26
(Increase) in Debtors		(316,644)	(793,653)
(Increase) / Decrease in Stock		(2,035)	1,635
Increase in Creditors - amounts falling due within one year		1,532,175	1,702,799
Deposit Interest		(16,737)	(16,064)
Bank Interest		174,075	181,171
Cash from Operations		4,263,784	3,832,738
Bank Interest Paid		(174,075)	(181,171)
Net Cash generated from Operating Activities		4,089,709	3,651,567
Cash flows from Investing Activities			
Deposit Interest Received		16,737	16,064
(Increase) / Decrease in Bank Deposits		(9,441,426)	4,085,613
Payments to acquire property, plant and equipment		(1,744,103)	(681,407)
Receipts fom sales of property, plant and equipment		680	0
Net cash from Investing Activities		(11,168,112)	3,420,270
Cash flows from Financing Activities			
Repayment of Borrowings		(793,332)	(793,332)
Net cash used in Financing Activities		(793,332)	(793,332)
Net increase/(decrease) in Cash and Cash Equivalents		(7,871,735)	6,278,505
Cash and Cash Equivalents at beginning of year		10,162,555	3,884,050
Cash and Cash Equivalents at end of year	9	2,290,820	10,162,555

Notes to the Financial Statements
For the year ended 31 December 2019

1. Accounting Policies

A. General information
The Health Products Regulatory Authority (HPRA) is a public statutory body established under the Irish Medicines Board Act 1995 (as amended). The principal place of business is at Earlsfort Centre, Earlsfort Terrace, Dublin 2. The Health Products Regulatory Authority is the competent Authority for the regulation of medicines, medical devices and other health products in Ireland.

B. Compliance with FRS 102

The financial statements of the HPRA for the year ended 31 December 2019 have been prepared in accordance with FRS 102 (the financial reporting framework applicable in the UK and Ireland, and promulgated by Chartered Accountants Ireland), as modified by the directions of the Minister for Health in relation to superannuation. In compliance with the directions of the Minister for Health, HPRA accounts for the costs of superannuation entitlements only as they become payable (see K). This basis of accounting does not comply with FRS102, which requires such costs to be recognised in the year in which the entitlement is earned. The HPRA is availing of the reduced disclosures allowed by FRS 102 in relation to legal provisions, in instances where full disclosure might prejudice seriously its position in relation to disputes with other parties on the subject matter of the provision. In all other respects, the financial statements comply with FRS 102.

C. Basis of preparation

The financial statements have been prepared under the historical cost convention. The following accounting policies have been applied consistently in dealing with items which are considered material in relation to the Health Products Regulatory Authority's financial statements.

D. Critical accounting estimates and judgements

The preparation of the financial statements requires management to make judgements, estimates and assumptions that affect the amounts reported for assets and liabilities as at the reporting date and the amounts reported for revenues and expenses during the year. However, the nature of estimation means that actual outcomes could differ from those estimates. The following may involve a higher degree of judgement and complexity:

(a) Provisions
Provisions for legal obligations which it knows to be outstanding at the period-end date. These provisions are generally made based on historical or other pertinent information, adjusted for recent trends where relevant. However, they are estimates of the financial costs of events that may not occur for some years. As a result of this and the level of uncertainty attaching to the final outcomes, the actual outturn may differ significantly from that estimated.

(b) Bad and Doubtful Debts
The HPRA makes an estimate of the recoverable value of trade and other receivables. The HPRA uses estimates based on historical experience in determining the level of bad debts, which the Authority believes will not be collected. These estimates include such factors as the current credit rating, the ageing profile, historical experience of the particular trade receivable and objective evidence of impairment of the asset. Any significant reduction in the level of bad debt provision would have a positive impact on the annual surplus/deficit. The level of provisioning required is reviewed on an on-going basis and has been disclosed in the notes to the financial statements.

Notes to the Financial Statements
For the year ended 31 December 2019

E. Revenue recognition

Revenue is measured at the fair value of the consideration received.

- In the case of applications for marketing authorisations (new applications, variations to existing authorisations, or transfers) and clinical trial applications, income is recognised on a straight line basis over the specified timeline for the processing of the application by the Authority.
- In the case of wholesale and manufacturing licences and maintenance of marketing authorisations, fees are payable annually and a full year's income is accrued in each financial year.

F. Expenditure recognition

Expenditure is recognised in the financial statements on an accruals basis.

G. Reporting currency and currency translation

The financial statements are prepared in euros. Transactions in currencies other than euro are recorded at the rates ruling at the date of the transactions or at a contracted date. Monetary assets and liabilities are translated into euro at the reporting date or at a contracted date. Exchange differences are dealt with in the statement of income and expenditure and retained revenue reserves.

H. Property, plant and equipment

Plant and equipment excluding Premises

Plant and equipment excluding premises are stated at cost less accumulated depreciation.

Depreciation is calculated in order to write off the cost of property, plant and equipment to their estimated residual values over their estimated useful lives by equal annual instalments.

The estimated useful lives of property, plant and equipment by reference to which depreciation has been calculated are as follows:

Fixtures and Fittings:	5 years
Computer Equipment :	3 years
Improvements to Premises :	10 years

Premises

The HPRA purchased its premises at Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2 on 22 December 2004. The value capitalised was equal to the purchase price plus those costs directly attributable to bringing the asset into use.

No depreciation has been calculated on the value of premises, as the remaining useful economic life is estimated to be greater than 50 years.

I. Taxation

The HPRA is exempt from liability to Corporation Tax under Section 227 of the Taxes Consolidation Act, 1997.

Notes to the Financial Statements
For the year ended 31 December 2019

J. Debtors

Known bad debts are written off and specific provision is made for any amount the collection of which is considered doubtful.

K. Superannuation

The superannuation scheme operated by the HPRA is in accordance with the Local Government (Superannuation Revision) (Consolidation) Scheme, 1986. It is an unfunded statutory scheme and benefits are met from current income as they arise.

The scheme is a defined benefit scheme for employees. No provision has been made in respect of benefits payable. Pension payments under the scheme are charged to the statement of income and expenditure when paid. Contributions from employees who are members of the scheme are credited to the statement of income and expenditure when received. The surplus/(deficit) for the year is shown both before and after superannuation deductions.

HPRA also operate the Single Public Service Pension Scheme. All new entrants into the public sector with effect from 1 January 2013 are members of this scheme, where all employee pension deductions are paid to the Department of Public Expenditure and Reform.

By direction of the Minister for Health, no provision has been made in respect of benefits payable in future years in relation to the Local Government (Superannuation Revision) (Consolidation) Scheme 1986 or the Single Public Service Pension Scheme.

In order to help meet the cost of benefits payable in future years, reserves have been split between retained reserves and superannuation reserves, which consist of employee superannuation contributions. This split is shown in note 12 - Movement on Income and Expenditure Reserves.

L. Provisions

A provision is recognised when the HPRA has a present obligation as a result of a past event, it is probable that this will be settled at a cost to the HPRA and a reliable estimate can be made of the amount of the obligation.

M. Library

No value has been placed on the books, audio-visual resources and electronic databases in the library. Expenditure on these items is written off in the year in which it is incurred.

N. Leases

All leases are treated as operating leases and the rentals thereunder are charged to the Statement of Income and Expenditure and Retained Revenue Reserves on a straight line basis over the lease period.

O. Loans

Loans are recognised initially at the transaction price (present value of cash payable, including transaction costs). Loans are subsequently stated at amortised costs. Interest expense is recognised on the basis of the effective interest method and is included in finance costs.

Loans are classified as current liabilities unless there is a right to defer settlement of the loan for at least 12 months from the reporting date.

Notes to the Financial Statements
For the year ended 31 December 2019

2. Property, plant and equipment	Fixtures and Fittings	Computer Equipment	Leasehold Improvements	Improvements To Premises	Premises	Total
	€	€	€	€	€	€
Cost						
Balance as at 1 January 2019	1,238,581	16,441,616	502,445	4,374,608	23,156,037	45,713,287
Additions for the year	85,977	1,387,110	271,016	-	-	1,744,103
Disposals for the year	(650)	(115,420)	-	-	-	(116,070)
As at 31 December 2019	1,323,908	17,713,306	773,461	4,374,608	23,156,037	47,341,320
Depreciation						
Balance as at 1 January 2019	1,196,283	15,579,197	502,445	4,007,532	-	21,285,457
Charge for the year	39,162	1,101,364	27,102	107,220	-	1,274,848
Disposals for the year	(650)	(114,789)	-	-	-	(115,439)
As at 31 December 2019	1,234,795	16,565,772	529,547	4,114,752	-	22,444,866
Net Book value at 31 December 2019	89,113	1,147,534	243,914	259,856	23,156,037	24,896,454
Net Book value at 1 January 2019	42,298	862,419	-	367,076	23,156,037	24,427,830

3. Income	2019	2018
	€	€
Fee Income		
Clinical Trials	389,916	210,844
Human Medicine - National Fees	7,034,900	6,927,684
Human Medicine - European Fees	9,197,663	7,311,717
Veterinary Medicine - National Fees	1,988,373	1,856,343
Veterinary Medicine - European Fees	1,691,326	1,662,060
Compliance Department	5,845,249	4,925,873
Medical Devices	1,715,249	1,565,944
	27,862,676	24,460,465
Movement in deferred revenue	70,200	(558,862)
	27,932,876	23,901,603
Dept Of Health Funding (Vote 38 Subhead E1)	4,964,255	4,316,000
Other Income (Note 4)	805,824	888,884
Total Income	33,702,955	29,106,487

Certain fees received by the Authority under the Irish Medicines Board Act 1995 (as amended), totalling €20,749,816 in 2019, shall be paid into or disposed of for the benefit of the Exchequer in such manner as the Minister for Public Expenditure and Reform directs.

The HPRA is in discussions with its parent department, as it is some years since the Minister has issued a directive in relation to the fees under Section 13 of the IMB Act.

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Notes to the Financial Statements
For the year ended 31 December 2019

4. Other Income

	2019	2018
	€	€
Conference Fee Income	12,860	181,842
Deposit Interest	16,737	16,064
(Loss)/Gain on Disposal of Fixed Assets	49	(26)
IT Income	714,875	614,250
Zambia Project Income	61,303	76,754
	805,824	888,884

5. Salaries and Wages

Basic Pay	19,622,110	18,265,668
Overtime	10,956	12,465
Allowances	178,300	169,636
Staff Short Term Benefits	19,811,366	18,447,769
Retirement Benefit Costs	1,153,648	885,825
Employer's Contribution to Social Welfare	1,986,755	1,826,620
Employer's Contribution to Single Scheme Pension	910,669	-
	23,862,438	21,160,214

The average number of staff employed during the year was 348 (2018 - 332).
Payroll numbers at 31 December 2019 can be analysed across the following departments:

Chief Executive	3	3
Compliance	63	63
Finance, Corporate & International	26	24
Human Products Authorisation & Registration	101	101
Human Products Monitoring	34	33
Human Resources & Change	10	9
IT & Business Services	18	21
Medical Devices	44	36
Quality, Scientific Affairs & Communications	12	13
Veterinary Sciences	35	32
Staff	346	335
Authority Members	7	7
Pensioners	46	39
	399	381

No termination or severance payments were made during the year. One such payment was made in 2018.

Additional superannuation contributions for Public Servants of €755,591 were deducted from staff during the year and paid over to the Department of Health. On 1 January 2019, in accordance with DPER circular 21/2018, the pension related deduction (PRD) was replaced by an additional superannuation contribution (ASC).

Pension deductions for Public Servants who are members of the Single Public Service Pension Scheme of €336,275 were deducted from staff during the year and paid over to the Department of Public Expenditure and Reform.

In agreement with our parent department and DPER, the HPRA have also paid over Single Scheme employer contributions since January 2019 for employees not employed in exchequer funded areas.

Notes to the Financial Statements
For the year ended 31 December 2019

Employee's short term benefits are categorised into the following bands:

Salary Band	2019	2018
€0 to €60,000	214	213
€60,001 to €70,000	54	47
€70,001 to €80,000	20	27
€80,001 to €90,000	16	11
€90,001 to €100,000	20	20
€100,001 to €110,000	15	10
€110,001 to €120,000	4	4
€120,001 to €130,000	2	1
€130,001 to €140,000	-	1
€140,001 to €150,000	-	-
€150,001 to €160,000	1	1
	346	335
Average Salary	€54.9K	€54.6K

Higher salaries relate primarily to scientific and other professional staff e.g. clinicians, pharmacists, veterinarians, lawyers etc and are in accordance with Department of Health salary scales.

For the purposes of this disclosure, short-term employee benefits in relation to services rendered during the reporting period include salary, overtime, allowances and other payments made on behalf of the employee, but exclude employer's PRSI.

6. Operating Costs

	2019 €	2018 €
Accommodation Costs	1,291,822	1,210,891
Travel, Representation and Training	973,179	1,304,837
Bank Charges and Interest	179,047	187,696
Legal Fees	2,344,387	657,437
Audit Fees (External and Internal)	34,305	32,791
Stationery, Publications, Postage and Communications	464,148	578,144
Consultancy	499,038	331,390
Sampling and Analysis	243,132	252,748
IT Costs	1,342,133	1,645,426
Document Storage	152,279	123,707
Telephone and Telecommunications	97,616	92,593
Movement on Bad Debt Provision	18,287	(532,095)
	7,639,373	5,885,565

Travel costs include an amount of €26,162 related to staff hospitality, and an amount of €432,060 related to travel and subsistence, of which €198,851 is national and €233,209 is foreign.

No costs were incurred in relation to client hospitality.

Legal fees are in relation to ongoing legal proceedings, and do not include any amounts in relation to conciliation, arbitration or settlement payments.

Consultancy costs comprise €127,669 related to public relations/marketing, €194,541 related to human resources/ pensions and €176,828 related to other.

Notes to the Financial Statements
For the year ended 31 December 2019

7. Debtors (all due within one year)

	2019	2018
	€	€
Trade Debtors	2,018,140	1,852,256
Prepayments	309,093	211,940
Other Debtors	187,751	134,144
	2,514,984	2,198,340

Trade debtors are shown net of the bad debt provision.

8. Creditors (amounts falling due within one year)

Trade Creditors	1,174,870	189,511
Accruals	8,692,902	8,129,067
Deferred Revenue	1,738,297	1,808,497
Revenue Commissioners	687,018	633,837
	12,293,087	10,760,912

9. Cash and Cash Equivalents

Cash at Bank and in Hand	772,549	4,027,728
Demand Deposits (Convertible to Cash on Demand)	1,518,271	6,134,827
	2,290,820	10,162,555

10. Short Term Deposits

Short Term Deposits (not immediately convertible to cash)	17,658,240	8,216,814
	17,658,240	8,216,814

11. Administration Expenses

Surplus for the year was calculated having charged:		
Auditor's Remuneration	20,000	18,000

Notes to the Financial Statements
For the year ended 31 December 2019

12. Movement on Income and Expenditure Reserves

	As At 01/01/2019 €	Income & Expenditure €	Transfer To Pension Reserve €	As At 31/12/2019 €
Retained Reserves	18,611,970	926,296	(400,000)	19,138,266
Staff Superannuation Contributions	10,876,143	691,855	400,000	11,967,998
	29,488,113	1,618,151	0	31,106,264

Our Audit and Risk Committee recommended the transfer of a further €400,000 in 2019 from retained reserves to the superannuation reserve as a result of a number of recent and upcoming retirements, where the costs are quite significant.

13. Long Term Liabilities

Mortgage

On 22 December 2004 the HPRA purchased its premises at Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2. The purchase was financed by way of a mortgage, secured on the premises of €20,400,000 over 20 years from Bank of Ireland Corporate Lending.

The HPRA is committed to making the following capital repayments on its mortgage:

	2019 €	2018 €
- within one year	793,332	793,332
- between one and five years	3,173,328	3,173,328
- after five years	20	793,352
	3,966,680	4,760,012

14. Interest Rate Exposure

The HPRA have taken all necessary steps to minimise its interest rate exposure by fixing 2/3s of the borrowings for the mortgage duration. The balance of the borrowings are fully offset by cash reserves. As the mortgage is at a fixed rate, the Authority has no interest rate exposure.

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Notes to the Financial Statements
For the year ended 31 December 2019

15. Financial Commitments

Accommodation Costs (Note 6) includes expenditure of €285,984 in relation to operating leases.

On 28 January 2005 the HPRA signed a leasehold interest in respect of the 5th floor, 6 Earlsfort Terrace, Dublin 2. At 31 December 2019 this lease had 2 years and 4 months remaining.

	2019 €	2018 €
The amounts due under this lease are as follows:		
- within one year	285,984	285,984
- between one and five years	381,312	667,296
- after five years	-	-
	667,296	953,280

On 11 June 2019 the HPRA signed a leasehold interest in respect of the 4th floor, 6 Earlsfort Terrace, Dublin 2. The lease included a seven month rent free period to 10 January 2020. At 31 December 2019 this lease had 14 years and 5.5 months remaining.

The amounts due under this lease are as follows:		
- within one year	360,735	-
- between one and five years	1,485,683	-
- after five years	3,508,230	-
	5,354,648	-

16. Capital Commitments

Contracted For (Contract Signed)	26,779	1,404,356
	26,779	1,404,356

Notes to the Financial Statements
For the year ended 31 December 2019

17. Authority Remuneration

	2019 Fees	2018 Expenses
	€	€
Ms. Ann Horan (Chairperson)	11,970	0
Mr. Pat Brangan	7,695	0
Mr. Wilfrid Higgins	7,695	0
Mr. David Holohan	7,695	78
Mr. Brian Jones	7,695	184
Dr. Elizabeth Keane	7,695	522
Prof. David Kerins	0	192
Prof. Caitriona O'Driscoll	0	692
Dr. Diarmuid Quinlan	7,695	235
	58,140	1,903

Up to the 15th February 2017, other than the Chairperson, no other Authority Member received a salary. On 16th February 2017, the Health (Miscellaneous Provisions) Act was enacted, which made provision for payment of fees to other Authority members, provided that they were in compliance with the 'one person one salary' principle. Two Authority members do not receive a fee under this principle.

Authority expenses comprise €1,719 domestic and €184 foreign.

18. Key Management Personnel Remuneration

	€	€
Chief Executive	157,031	151,500
Senior Management	812,419	832,051
	969,450	983,551

All payments to key management personnel were in respect of salaries and short term employee benefits. No post-employment benefits or termination benefits were paid.

The Chief Executive's and senior management's pension entitlements do not extend beyond the standard entitlements in the model public sector defined benefit superannuation scheme.

19. Related Party Transactions

The HPRA adopts procedures in accordance with the guidelines issued by the Department of Public Expenditure and Reform (DPER) covering the personal interests of Authority members. A register of such interests is maintained. In addition to the DPER guidelines, as a regulator the HPRA has strict conflict of interest and disclosure requirements in relation to any interactions with a regulated body, which are updated annually. There have been no transactions with related parties which require disclosure under Financial Reporting Standard 102.

20. Prompt Payment of Accounts

The Health Products Regulatory Authority (HPRA) confirms that it is complying with EU law in relation to prompt payment of accounts.

Notes to the Financial Statements
For the year ended 31 December 2019

21. Exchange Rates

The exchange rates used in preparing these financial statements were as follows:

2019	€1 = STG £0.85369
2018	€1 = STG £0.85680

22. Provisions

The HPRA has been notified of a number of legal proceedings or potential proceedings. The Authority has provided in full for its 'best estimate' of the expenditure it is likely to incur in relation to those cases. The Authority is availing of the reduced disclosures allowed by FRS 102 in instances where full disclosure might prejudice seriously its position in a dispute with other parties on the subject matter of the provision.

23. Going Concern

The HPRA has a reasonable expectation, at the time of approving the financial statements, that the HPRA has adequate resources to continue its operations. For this reason, the HPRA continues to adopt the going concern basis in preparing the financial statements.

The Covid-19 pandemic has impacted how the HPRA operates, with all staff substantially moved offsite and resources diverted to managing implications of the pandemic. The Authority assesses this event to be a non-adjusting post balance sheet event in relation to the 2019 financial results. No impact is expected in relation to the 2019 financial statements and currently we are not predicting a significant financial impact for 2020, although due to the nature of the pandemic, the final impact cannot be estimated at this point. HPRA's income is derived from the pharmaceutical, medical devices and related industries, which continue to operate throughout the pandemic and therefore are financially less impacted than those industries which have closed or have limited output.

24. Approval of Financial Statements

The financial statements were approved by the Authority of the HPRA on 07 May 2020.

Appendix 1

2019 Committee Members

Management Committee

Dr. Lorraine Nolan
Chief Executive

Ms. Rita Purcell
Deputy Chief Executive

Dr. Gabriel Beechinor
Director of Veterinary Sciences

Ms. Sinead Curran
(Appointed December 2019)
Director of Human Products Monitoring

Dr. Caitríona Fisher
Director of Quality, Scientific Affairs and Communications

Dr. Joan Gilvarry
(Retired May 2019)
Director of Human Products Monitoring

Mr. Kevin Horan
(Resigned February 2019)
Director of Information Technology and Business Services

Mr. John Lynch
Director of Compliance

Dr. Niall MacAleenan
Deputy Director of Medical Devices

Ms. Lynsey Perdisatt
Director Human Resources and Change

Ms. Grainne Power
Director of Human Products Authorisation and Registration

Authority (Board)

Ms. Ann Horan – Chairperson

Dr. Patrick Brangan
(Term ended December 2019)

Mr. Wilfrid Higgins
(Term ended December 2019)

Mr. David Holohan

Mr. Brian Jones

Prof. Elizabeth Keane

Prof. David Kerins
(Appointed March 2019)

Prof. Caitriona O'Driscoll

Dr. Diarmuid Quinlan

Audit Committee

Dr. Patrick Brangan – Chair

Mr. David Holohan

Prof. Elizabeth Keane

Advisory Committee for Human Medicines

Prof. David Kerins – Chair
(appointed June 2019)

Dr. Kevin Connolly

Prof. Desmond Corrigan

Ms. Maria Egan

Prof. Tom Fahey

Prof. David Kerins

Ms. Fionnuala King

Prof. Patrick Murray

Dr. Fionnuala Ní Ainle

Dr. Brian O'Connell

Mr. Ronan Quirke

Dr. Patrick Sullivan

Advisory Committee for Veterinary Medicines

Dr. Patrick Brangan – Chair

Dr. Ruadhrí Breathnach

Ms. Eugenie Canavan

Dr. Robert Doyle

Dr. Helena Kelly

Dr. Nola Leonard

Dr. Edward Malone

Dr. Bryan Markey

Dr. Ciaran Mellett

Dr. Warren Schofield

Dr. Robert Shiel

Dr. Christina Tlustos

Advisory Committee for Medical Devices

Mr. Wilfrid Higgins – Chair

Dr. Vivion Crowley

Mr. Ger Flynn

Dr. Fergal McCaffrey

Ms. Margaret O'Donnell

Prof. Martin O'Donnell

Prof. Richard Reilly

Prof. Mary Sharp

Mr. Sean-Paul Teeling

Prof. Sean Tierney

Clinical Trial Sub-Committee of Advisory Committee for Human Medicines

Dr. Patrick Sullivan – Chair
Dr. Liam Bannan
Dr. Geraldine Boylan
Dr. Paul Browne
Dr. Peter Crean
Prof. Lee Helman (CT Expert)
Dr. Filip Janku (CT Expert)
Dr. Catherine Kelly
Dr. Patrick Morris
Dr. Catherine McHugh
Dr. Thomas Peirce
Dr. Bryan Whelan
Dr. Jennifer Westrup

Experts Sub-Committee of the Advisory Committee for Human Medicines

Prof. David Kerins – Chair *(appointed June 2019)*
Dr. Fionnuala Breathnach
Dr. Linda Coate
Dr. Kevin Connolly
Mr. James Colville
Dr. Noreen Dowd
Dr. Stephen Eustace
Prof. Stephen Flint
Dr. Tim Fulcher
Dr. Joseph Galvin
Dr. Sheila Galvin
Dr. Patrick Gavin
Dr. Paul Gallagher
Dr. Kevin Kelleher
Dr. Catherine Kelly
Dr. Mary Keogan
Prof. David Kerins
Dr. Mark Ledwidge
Dr. Frank Murray
Dr. Yvonne O'Meara
Dr. Cormac Owens
Dr. Jogin Thakore
Dr. Gerry Wilson

Advisory Sub-Committee for Herbal Medicines

Prof. Des Corrigan – Chair
Dr. James Barlow
Dr. Kevin Connolly
Mrs. Ingrid Hook
Ms. Claudine Hughes
Ms. Anna-Maria Keaveney
Dr. Celine Leonard
Dr. Donal O'Mathuna
Dr. Camillus Power
Dr. Helen Sheridan
Dr. Emma Wallace

Appendix 2

Presentations 2019

Educational / Professional Development Presentations and Training

Institution	Course	Presentation Title
BVL (Germany)	Training on Quality Assessment of Veterinary Medicines	New Veterinary Legislation - Focus on Quality Aspects
DCU	Chemistry / Pharmaceutical Chemistry	Regulatory Affairs and Risk Management
DCU / TCD	Bioprocess Engineering	Regulation of Medicines
DCU / TCD	Bioprocess Engineering	Regulation of Biologics
GMIT	Medtech Regulatory Affairs	New European Regulations on Medical Devices
GMIT	Medtech Regulatory Affairs	Medical Devices Regulation – An Introduction
Infarmed / ANSM	Training Workshop	Update on JAMS WP5 Clinical Process and resource Development
IPPOSI	Patient Education Programme	Various Presentations: Regulatory Affairs, Medicinal Product Safety and Pharmacovigilance
Irish Designated Veterinarians Group / UCD	Training Workshop	Responsibilities of Designated Veterinarians
LAST Ireland	Laboratory Animal Science and Training	HPRA Implementation of Directive 2010/63/EU
Law Society of Ireland	Diploma in Healthcare Law	Regulating Health Products - The HPRA
Letterkenny IT	Veterinary Nursing	The Regulation of Veterinary Medicines in Ireland
Pharmacists in Industry, Education and Regulatory	Autumn CPD Meeting and AGM	Multi Stakeholder Approach to Managing Shortages
RCSI	Nurse / Midwife Prescribing	The Role of the HPRA and Pharmacovigilance
St John's Cork	Veterinary Nursing	The Regulation of Veterinary Medicines in Ireland
Swiss Medic	GMP Training for Inspectors	Reprocessing and Reworking
TCD	Bioengineering	Regulation of Medical Devices
TCD	Hospital Pharmacy	Pharmacovigilance and Risk Management

TCD	Immunotherapeutics	Regulation of Medicines
TCD	Immunotherapeutics	Regulation of Biologics
TCD	Pharmaceutical Manufacturing Technology	HPRA and the Role of the Pharmacopoeia in the Regulation of Medicines
TCD	Pharmaceutical Medicine	Regulation of ATMPs
TCD	Pharmaceutical Medicine	Adverse Event / Reaction Reports arising from Clinical Trials
TCD	Pharmaceutical Medicine	Pharmacovigilance Inspections
TCD	Pharmaceutical Medicine	Overview of Pharmacovigilance
TCD	Pharmaceutical Medicine	Pharmacovigilance and Risk Management
TCD	Pharmaceutical Medicine	Communication of Drug Safety Data & Overview of the WHO Programme for International Drug Monitoring
TCD	Pharmaceutical Medicine	Workshop: Completion of Individual Case Reports (SUSARs and ICSRs)
TCD	Pharmaceutical Medicine	EU Falsified Medicines Directive
TCD	Pharmaceutical Medicine	GCP Inspections
TCD	Pharmaceutical Medicine	Product Recalls and MA Withdrawals
TCD	Pharmacy	Overview of Pharmacovigilance
TCD	Pharmacy	Quality Defect Reporting Workshop
TCD	Pharmacy	Quality Defect Reporting, Investigations and Recall Management Workshop
London School of Hygiene & Tropical Medicine	Vaccines Short Course	Licensing Vaccines: Clinical Considerations
The State Laboratory	Training Seminar	HPRA Enforcement
TOPRA	Training Workshop	Medical Devices Legislation
UCD	Clinical Biomarkers (Medicine)	Overview of the IVD Regulation
UCD	Medicine / Pharmacy	Notification of Adverse Reactions
UCD	Prescribing Medication	The Role of the HPRA and Pharmacovigilance
UCD	Regulatory Affairs	Regulation of Clinical Trials

Regulatory Presentations

Event / Organiser	Presentation Title
ACB Scientific Meeting	Role of the HPRA in IVD Regulation
Analytical Technologies Europe 2019 - CASSS	Post-Approval Flexibility in Analytical Methods
An Garda Síochána - Seminar	Enforcement of Online Sales of Medicines
Animal and Plant Health Association	Veterinary Medicines – An Update on Regulatory Issues
Animal Health Awards	HPRA Introduction
ANSM	JAMS WP5 – Update on Outputs
BioPharmaChem Ireland – Data Analytics Workshop	Data Analytics and GMP – A Regulatory Perspective
Centre for Cell Manufacturing Ireland	Regulatory Developments for ATMPs
Clinical Research Development Ireland	HPRA supports for Clinical Research
DIA Brexit Summit	Centralised Activities – Ireland: Challenges and Preparedness
European Commission/ ECDC – One Health AMR Country Visit	Medicines Regulation: Opportunities to Contribute to Addressing AMR
European Medicines Agency	New Approaches to Improve Benefit-risk Assessment of Veterinary Medicinal Products
FSAI	An Overview of the Cosmetovigilance System
G2 Risk Summit	Combating Online Medical Product Crime through Operation Pangea
GIRP (European Healthcare Distribution Association)	Overview on the 'Use and Learn Phase' of FMD in Ireland
Global Pharmaceutical Manufacturing Leadership Forum	PIC/S GMP Inspection Reliance Initiative
Health Research Board	Controlled Drugs Overview
IMSTA	Brexit Preparedness – HPRA Perspective
Information Day: EU Commission Public Health Programme	Joint Action on Market Surveillance of Medical Devices
Irish Cosmetic and Detergent Association	Cosmetic Products - A Regulatory Overview
Irish Exporters Association	Patient Safety and the Supply Chain
Irish German Healthcare Forum	Implementation of the EU Device Regulations
Irish Medtech Association	Implementation of the EU Device Regulations
Irish Medtech Association	Implementation of the EU Medical Devices Regulations
Irish Ringers Meeting	Role of the HPRA in Wildlife Research
Klifovet AG & AnimalhealthEurope	New EU Veterinary Medicines Regulation
Medico-Legal Society of Ireland	Medicrime in a Cyber World
OCLAESP (France)	Operation MISMED 2: Results and Observations from Ireland
OMCL Network Annual Meeting	Future Testing Strategies of the Network for MRP and DCP Products

OMCL Network Annual Meeting	HMA Risk Assessment and Test Recommendation Tool
OMCL Network Annual Meeting – CAP	Update on Heparin Crude Surveillance Activities
Parenteral Drug Association (PDA)	Annex 1 Revision
Parenteral Drug Association (PDA)	Demonstrating the Effectiveness of the PQS from a QRM Perspective
Parenteral Drug Association (PDA)	PIC/S GMP Inspection Reliance Initiative
PIC/S Annual Seminar	Application of Quality Risk Management to Inspection Planning for Sterile Site Inspection
PIC/S Expert Circle Meeting	Cross Contamination Considerations – Introducing Mew Molecule into a Facility
PLS Pharma Responsible Person Forum	HPRA: Expectations and Deficiencies
Premier Irish Industrial Hemp Conference	Application Process for a Licence to Cultivate Hemp
QP Forum – TCD	ICH Q12 – What it might mean for QPs
QP Forum – TCD	Regulatory Updates
Research Quality Association – Forum	Safety Features
Revenue Customs Service - Seminar	Enforcement of Online Sales of Medicines
Taking Care of Business (DBEI)	Supporting Innovation through Regulation and Science
TOPRA Annual Symposium	A Regulators Perspective on ICH Q12
TOPRA Annual Symposium	Brexit Checklist
TOPRA Annual Symposium	Clinical Data Requirements with the MDR – Competent Authority Perspective
TOPRA Annual Symposium	Clinical Trials Regulation
TOPRA Annual Symposium	Guidance on Quality Requirements for Drug–Device Combinations
TOPRA Annual Symposium	Horizon Scanning within the EU-Innovation Network
TOPRA Annual Symposium	Horizon scanning within the EU-Innovation Network
TOPRA Annual Symposium	Implementation of the Device Regulations – An Overview
TOPRA Annual Symposium	IVDR Preparedness – National Competent Authority Perspective
TOPRA Annual Symposium	Medical Devices Post-market Surveillance
TOPRA Annual Symposium	New Veterinary Medicines Regulation - Impact on the Authorities
TOPRA Annual Symposium	New Veterinary Medicines Regulation – The Impact on Authorities
TOPRA Annual Symposium	Novel Veterinary Medicines Development: A CVMP Perspective
TOPRA Annual Symposium	Progress on MDR/IVDR – Competent Authority Perspective
TOPRA Annual Symposium	Veterinary Medicines – Life after Brexit
TU Dublin Conference	Demonstrating the Effectiveness of the PQS from a QRM Perspective

Appendix 3

Publications and Articles 2019

Drug Safety Newsletters

Edition	Topics
April 92nd Edition	– Lemtrada (alemtuzumab) – Use restricted while European Medicines Agency (EMA) review is ongoing – SGLT-2 inhibitors – Risk of Fourniers Gangrene – Cobicistat boosted darunavir and elvitegravir – Avoid use in pregnancy due to potential risk of virological failure in second and third trimester – Direct-Acting Antivirals for chronic hepatitis C – Risk of hypoglycaemia in patients with diabetes – Biotin – Interference with clinical laboratory tests – Direct Healthcare Professional Communications published on the HPRA website since the last Drug Safety Newsletter
June 93rd Edition	– Domperidone containing medicines – No longer approved for use in children due to lack of efficacy – Direct oral anticoagulants (DOACs) – Not recommended in patients with antiphospholipid syndrome (APS) due to possible increased risk of recurrent thrombotic events – Xelijanz (tofacitinib) – Use restricted in patients at high risk of pulmonary embolism while European Medicines Agency (EMA) review is ongoing – Direct Healthcare Professional Communications published on the HPRA website since the last Drug Safety Newsletter
August 94th Edition	– Montelukast – Reminder of the risk of neuropsychiatric reactions and product information update – Modafinil-containing medicines – Potential risk of congenital malformations when administered during pregnancy – RoActemra (tocilizumab) – Rare risk of serious hepatic injury including acute liver failure requiring transplantation – Febuxostat – Increased risk of cardiovascular death and all-cause mortality in patients treated with febuxostat in the CARES study – Darzalex▼ (daratumumab) – Risk of Hepatitis B reactivation – Direct Healthcare Professional Communications published on the HPRA website since the last Drug Safety Newsletter

December 95th Edition	– Methotrexate – New measures to avoid dosing errors – SGLT2 inhibitors – Updated advice on monitoring ketone bodies in patients hospitalised for major surgical procedures or acute serious medical illnesses – Ingenol mebutate (Picato▼) – Use with caution in patients with a history of skin cancer – Fingolimod (Gilenya▼) – Contraindication in pregnant women and in women of child bearing potential not using effective contraception – Levothyroxine – Close monitoring recommended in the event of a brand change – Parenteral nutrition products for neonates and children below 2 years of age – Protect from light until administration is completed – Direct Healthcare Professional Communications published on the HPRA website since the last Drug Safety Newsletter

Human Medicines Articles – External Publications

Month	Publication	Topics
January	MIMS	– Fluoroquinolone antibiotics – EU review advises restrictions for certain infections and warns of rare but serious long lasting adverse reactions
	MIMS Multiple Sclerosis Supplement	– Adverse Reaction Reporting – Reminder
February	MIMS	– Mycophenolate – Reminder of updated contraceptive advice
	MIMS Respiratory Supplement	– Fluoroquinolone antibiotics – EU review advises restrictions for certain infections and warns of rare but serious long lasting adverse reactions
March	IMF	– Fluoroquinolone antibiotics – EU review advises restrictions for certain infections and warns of rare but serious long lasting adverse reactions
	MIMS	– SGLT-2 inhibitors – Risk of Fournier's gangrene
	MIMS Cardiovascular Supplement	– Clarithromycin – Reminder on cardiovascular safety and risk minimisation advice
April	MIMS	– Valproate (Epilim) – Reminder about contraindications, warnings and measures to prevent exposure during pregnancy
	MIMS General Supplement	– Adverse Reaction Reporting
May	MIMS	– Direct-Acting Antivirals for Chronic Hepatitis C – Risk of hypoglycaemia in patients with diabetes
	MIMS Oncology Supplement	– Hydrochlorothiazide (HCTZ) – Risk of non-melanoma skin cancer (NMSC)
June	MIMS	– Insulin-containing products – Risk of medication errors associated with extraction of insulin from pre-filled pens and cartridges for reusable pens

July / August	MIMS	– Systemic fusidic acid and interaction with statins – Reminder of risk of rhabdomyolysis
	MIMS Respiratory Supplement	– Montelukast – Reminder of risk of neuropsychiatric reactions and product information update
September	IMF	– Domperidone-containing medicines – No longer approved for use in children due to lack of efficacy
	MIMS	– Xofigo (radium-233 dichloride) – Reminders of restrictions for use
	MIMS Pain Supplement	– Gabapentin – Respiratory depression without concomitant opioid use
October	MIMS	– Domperidone-containing medicines – No longer approved for use in children due to lack of efficacy
	MIMS Women's Health Supplement	– Fingolimod (Gilenya▼) – Contraindicated in pregnant women and in women of child bearing potential not using effective contraception
November	MIMS	– Picato – Use with caution in patients with a history of skin cancer
	MIMS Type 2 Diabetes Supplement	– SGLT2 inhibitors – Updated advice on monitoring ketone bodies in patients hospitalised for major surgical procedures or acute serious medical illnesses
December	MIMS	– Parenteral nutrition products for neonates and children below 2 years of age – Protect from light until administration is completed
	MIMS Compendium	– Methotrexate – New Measures to Avoid Dosing Errors

Veterinary Medicines Articles – External Publications

Publication	Article Title
Veterinary Ireland Journal	Initial Assessment of the Impact of the New European Regulation on Veterinary Medicines
It's Your Field	Regulatory Controls on the Supply of Veterinary Medicines in Ireland
It's Your Field	Authorisation of Veterinary Medicines in Ireland
It's Your Field	Veterinary Pharmacovigilance
It's Your Field	The Role of The HPRA in Animal Research in Ireland

Appendix 4

European and National Committee / Working Group Participation

Committee/Working Group	Organisation	Meetings in 2019
Counterfeiting of Medical Products (CMED)	Council of Europe	1
Market Surveillance Forum	Department of Business, Enterprise and Innovation	4
Controlled Drugs Cross Border Group	Department of Health	2
Early Warning and Emerging Trends Group	Department of Health	4
Medical Cannabis Access Programme	Department of Health	5
National Clinical Effectiveness Committee (NCEC)	Department of Health	1
Safety Features on Medicines – National Coordination Group	Department of Health	10
National Interdepartmental AMR Consultative Committee	Departments of Health / Agriculture, Food and the Marine	1
Committee for Cosmetics and Consumer Health	EDQM	3
Committee for Cosmetics and Consumer Health and European Network of OCCLs – Joint meeting	EDQM	1
European Network of Official Cosmetics Control Laboratories (OCCL)	EDQM	1
OMCL Network Active Pharmaceutical Ingredient (API) Working Group	EDQM	1
OMCL Network Advisory Group	EDQM	1
OMCL Network Centrally Authorised Products (CAP) Working Group	EDQM	1
OMCL Network Falsified Medicines Working Group	EDQM	2
OMCL Network Mutual Recognition and Decentralised procedures (MRP/DCP) Working Group	EDQM	1
Committee for Advanced Therapies (CAT)	EMA	11
Committee for Herbal Medicinal Products (HMPC)	EMA	5
Committee for Medicinal Products for Human Use (CHMP)	EMA	11
Committee for Medicinal Products for Veterinary Use (CVMP)	EMA	11
Committee for Orphan Medicinal Products (COMP)	EMA	11

Committee/Working Group	Organisation	Meetings in 2019
Good Clinical Practice (GCP) Inspectors' Working Group (including training seminar)	EMA	1
Good Manufacturing and Distribution Practice (GMDP) Inspectors' Working Group / Sub-group	EMA	4
Heparin Working Group	EMA	3
Management Board	EMA	4
Opioid Initiative Steering Committee	EMA	2
Paediatric Committee (PDCO)	EMA	12
Pharmacovigilance (PV) Inspectors' Working Group	EMA	1
Pharmacovigilance Risk Assessment Committee (PRAC)	EMA	11
Pharmacovigilance Working Party - Veterinary	EMA	3
Quality Defects - Best Practices Working Group	EMA	1
Quality Defects and Rapid Alert Working Group	EMA	2
Quality Working Party	EMA	2
Scientific Advice Working Party - Human	EMA	11
Scientific Advice Working Party – Veterinary	EMA	11
Signal Management Review Technical Working Group (Methods) – PRAC	EMA	4
Signal Management Review Technical Working Group (SMART) Processes – PRAC	EMA	5
Veterinary Medicines Regulation – Drafting of implementing Acts	EMA	4
Competent Authorities for Organ Donation and Transplantation	European Commission	1
Competent Authorities for Tissues and Cells	European Commission	1
Expert Group on Clinical Trials	European Commission	4
Expert Group on Precursor Chemicals	European Commission	2
Expert Working Group on Safety Features (meetings, telecons & workshop with EMVO)	European Commission	8
IVD Classification Working Group	European Commission	7
IVD Technical Group	European Commission	4
IVD-CIE Working group	European Commission	3
Joint Action Market Surveillance of Medical Devices (MDs) (including telecon)	European Commission	6
Medical Device – Vigilance MIR Form Development	European Commission	4
Medical Device Clinical Investigation and Evaluation Working Group	European Commission	2
Medical Device Compliance and Enforcement Working Group (COEN)	European Commission	2
Medical Device Coordination Group	European Commission	6
Medical Device Expert Group Vigilance Working group	European Commission	2

Committee/Working Group	Organisation	Meetings in 2019
Medical Device Periodic Safety Update Reports Working Group	European Commission	2
Medical Device Regulatory Committee	European Commission	1
Medical Device Vigilance Eudamed Working Group	European Commission	2
National Contact Points for the implementation of Directive 2010/63/EU	European Commission	2
New Emerging Technologies - Software WG	European Commission	1
Nomenclature Taskforce	European Commission	2
Notified Body Operations Group	European Commission	4
NBO Taskforce – Sampling	European Commission	3
Organ Registries	European Commission	1
Platform of European Market Surveillance Activities in Cosmetics (PEMSAC) – Market Surveillance	European Commission	1
Standing Committee on Cosmetic Products	European Commission	2
Sub-group on Borderline Issues relating to Cosmetics	European Commission	1
Unique Device Identifier	European Commission	5
Working Group on Cosmetic Products	European Commission	3
Interpretation Guide for Harmonised Assessment Checklist for Audits of GMP Inspectorates	European Commission / EMA / HMA / PIC/S	3
Authorisation of Preparation Process for Blood, Tissues and Cells (GAPP Work Package Five)	European Commission / National Competent Authorities	2
Inspections Expert Subgroup (IES) Work Cluster IV (Blood, Tissues and Organs)	European Commission / National Competent Authorities	1
SoHO Vigilance Expert Sub-group (VES) (Blood, Tissues & Cells and Organs)	European Commission / National Competent Authorities	2
Operations / Liaison Meetings	Europol	6
Food Fraud Task Force	Food Safety Authority of Ireland (FSAI)	2
Clinical Trials Facilitation Group (CTFG)	HMA	6
Co-ordination Group for Mutual Recognition and Decentralised procedures – Veterinary (CMDv)	HMA	11
Co-ordination Group for Mutual Recognition and Decentralised procedures – Human (CMDh)	HMA	11
Heads of Medicines Agencies Biannual Meetings	HMA	2
Homeopathic Medicinal Products Working Group	HMA	2
Management Group (including telecons)	HMA	15
Pharmacovigilance Work-sharing Procedures Working Party	HMA	11

Committee/Working Group	Organisation	Meetings in 2019
Risk-based Surveillance Testing – Drafting Group (including telecons)	HMA	5
Working Group of Communications Professionals	HMA	2
Working Group of Enforcement Officers (WGEO) (including management committee)	HMA	4
Working Group of Quality Managers	HMA	2
Operational Group on Borderline and Combination Products	HMA / CAMD	1
EU Innovation Network (EU-IN)	HMA / EMA	2
National Cosmetics Surveillance Forum	HSE / HPRA	4
International Coalition of Medicines Regulatory Authorities (ICMRA)	ICMRA	2
Innovation Network	ICMRA	3
International Medical Device Regulators Forum (IMDRF) Management Committee	IMDRF	1
Revision of ICH Q9 Guideline	International Conference on Harmonisation	4
Operation Pangea / Liaison Meetings	Interpol	5
Competent Authorities for Medical Devices (CAMD)	National Competent Authorities	2
Next Generation Biologics Forum (various parties)	National Institute for Bioprocessing, Research and Training (NIBRT)	1
Permanent Forum on International Pharmaceutical Crime (PFIPC)	PFIPC	2
Pharmaceutical Inspection Co-Operation Scheme (PIC/S) Committee of Officials	PIC/S	1
PIC/S Expert Circle on Quality Risk Management (QRM) (including training seminar and telecons)	PIC/S	13
PIC/S Sub-Committee on Compliance (including telecon)	PIC/S	2
PIC/S Sub-Committee on Harmonisation	PIC/S	4
National Immunisation Advisory Committee	RCPI / Department of Health	3
Expert Group meeting on Falsified Medicinal Products	UN Office of Drugs and Crime	1
Member State Mechanism on Substandard and Falsified Medical Products	WHO	1

HPRA

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